EVOLUTION CAPITAL

ILA | INITIATION REPORT | HEALTHCARE

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Biodefense: Securing the Stockpile for Marburg

Island Pharmaceuticals Ltd

Recommendation	**Spec Buy**
Price Target	**$0.83**
Share Price	**$0.495**
TSR	**68%**

Island is seeking to commercialise Galidesivir, an antiviral backed by over US$70 million in prior US government funding, suitable for biodefense. The asset targets Marburg virus and is eligible for the FDA's "Animal Rule". This rare pathway allows for approval without human efficacy trials, relying instead on animal survival data. Historical studies in primates demonstrated ~94% survival against Marburg, significantly de-risking the remaining regulatory path.

Galidesivir Market Opportunity

Marburg Virus Disease (MVD) is a severe haemorrhagic fever clinically similar to Ebola, with a case fatality rate that has reached up to 90% in past outbreaks. Increasing outbreak frequency in Africa, including recent cases in Rwanda and Tanzania, has elevated Marburg to a Tier 1 biodefense priority. Yet, with no FDA-approved vaccines or treatments currently available, a critical gap exists in national preparedness, creating a potentially monopoly-like position for the first approved therapeutic to secure dominant government stockpile contracts.

Near-Term Lucrative Commercial Potential

The commercial thesis is underpinned by two near-term, high-value monetization events. First, FDA approval triggers the award of a Priority Review Voucher (PRV), a liquid regulatory asset with a secondary market value of ~US100-155 million. Second, approval positions Galidesivir as a critical therapeutic for the US Strategic National Stockpile (SNS), unlocking potential multi-year procurement contracts comparable to recent precedents exceeding US$100 million. This is a proven, lucrative market: comparable biodefense assets have secured massive recurring contracts, including Emergent BioSolutions' US$1.25 billion BioThrax procurement, SIGA Technologies' US$629 million TPOXX contract, and Chimerix's US$680 million award for Tembexa.

Future Flexibility: ISLA-101 Antiviral Program for Dengue

This program is is complemented by ISLA-101, a repurposed dengue fever antiviral. With Phase 2a data demonstrating prophylactic efficacy and a safety database from prior oncology trials, ISLA-101 provides exposure to a massive global endemic market distinct from the binary economics of the Marburg program. Importantly, upon FDA approval, ISLA-101 may also be eligible for its own Tropical Disease Priority Review Voucher and inclusion in the SNS or military stockpiles for troop protection, effectively doubling the company's exposure to high-value regulatory and government procurement catalysts.

Island Pharmaceuticals ultimately offers investors a funded, expedited regulatory shot on goal, where a single animal study acts as the gateway to potentially transformative cash flows.

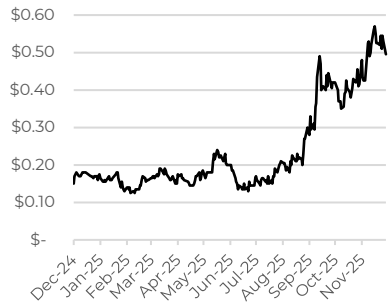
Key Catalysts

- **Q1 CY26:** Commencement of pivotal NHP study (Galidesivir).
- **Q2 CY26:** Pivotal NHP data readout (Validation of 94% survival signal).
- **CY27:** Potential FDA Approval, PRV Award, and SNS Contract execution.

Company Profile

Market Cap	$133.2M
Enterprise Value	$125.9M
SOI (diluted)	269.1M
Free Float	48.6%
ADV (3-month)	$416k
52-Week Range	$0.12 - $0.63

Price Performance



%	1M	3M	12M
Absolute	8.8%	83.3%	230%
ASX/S&P200	-2.0%	-2.8%	2.4%

Company Overview

Island Pharmaceuticals (ASX: ILA) is an antiviral drug developer advancing two clinical-stage assets: Galidesivir, a broad-spectrum antiviral targeting Marburg virus under the FDA's expedited Animal Rule pathway, and ISLA-101, a repurposed oral antiviral for dengue. Galidesivir has demonstrated ~94% survival in Marburg non-human primate studies and benefits from >US$70m in historic US government investment, positioning it for a Priority Review Voucher and potentially lucrative US Strategic National Stockpile contracts. ISLA-101 has shown prophylactic anti-dengue activity in a controlled human infection model, offering exposure to a large global endemic market. Together, these programs give ILA a near-term, de-risked regulatory pathway with meaningful upside through PRV monetisation and government procurement.

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Investment Thesis

Galidesivir Program: Expedited Path to Significant Cashflow

Island Pharmaceuticals is advancing Galidesivir, a broad-spectrum antiviral, through a expedited regulatory pathway targeting the lethal Marburg virus. The US FDA has endorsed development under the "Animal Rule", which allows approval based on animal efficacy data when human trials are unfeasible for highly lethal diseases. This means Galidesivir can be approved for Marburg without human efficacy trials, dramatically reducing development time and clinical risk. Galidesivir already has strong preclinical and clinical proof-of-concept: in non-human primates infected with Marburg, it achieved ~94% survival versus 0% for placebo, with certain dosing regimens even showing 100% survival. Coupled with robust Phase 1 safety data in humans, these results de-risk the program's efficacy and safety profile.

Upon FDA approval for Marburg, Galidesivir would earn a Priority Review Voucher (PRV) – a valuable, tradable FDA voucher granting expedited review for another drug. PRVs have historically sold for US$100-155 million on the secondary market, offering a potentially immediate monetization opportunity for Island. In parallel, the company is positioning Galidesivir as a critical countermeasure for government stockpiles, aiming to supply the US Strategic National Stockpile (SNS) with Marburg antiviral doses. Notably, past multi-year SNS procurement contracts for similar biodefense products have ranged from ~US$100 million up to US$1.2 billion per product. This dual pathway (PRV sale + government stockpile contracts) underpins a potentially lucrative commercial strategy, wherein FDA approval could rapidly translate into significant non-dilutive cash flows.

Importantly, Island's strategy is capital-efficient and low-risk. The Galidesivir program came with over US$70 million of prior US government R&D investment, meaning much of the expensive groundwork (preclinical studies, manufacturing, Phase 1 trials) is already done.

ISLA-101 Program: Repurposing a Safe Drug for a Major Unmet Need

ISLA-101 represents a second value driver for Island, targeting dengue – a high-burden tropical disease with no approved antivirals and constrained vaccine utility – via repurposing fenretinide, a compound with an extensive legacy safety database and encouraging signals from the PROTECT dengue human infection study. In that model, ISLA-101 prophylaxis reduced viremia and symptom burden versus placebo, and in a virus capable of causing severe, sometimes fatal complications, any statistically robust improvement over placebo is a meaningful proof-of-concept signal. Approval of ISLA-101 for dengue could qualify for a Tropical Disease PRV, creating a second monetizable voucher, and position the drug for inclusion in the US Strategic National Stockpile as well as analogous national and multilateral stockpiles in dengue-affected regions. Together, this establishes ISLA-101 as a higher-risk but potentially high-reward program that complements the binary, government-driven Marburg opportunity with exposure to large endemic, travel and government-preparedness markets.

Island Pharmaceuticals offers a compelling investment case: a near-term regulatory path with minimal clinical trial risk, potential for rapid, large-scale financial returns (via PRV and stockpile sales), and a focused plan to deliver efficient shareholder returns through strategic use of an expedited approval and commercial strategy.

Catalysts

The next 6-9 months are execution-focused, centering on finalizing the protocol with the FDA and commencing the NHP study. The major value-inflection point is the Q2 CY26 data readout from the animal study. Success there effectively validates the entire Animal Rule thesis and brings the PRV monetization (CY27) into clear view.

Estimated Timing	Program	Event / Catalyst	Impact / Significance
Q4 CY25	Galidesivir	Finalize BSL-4 Research Agreement	Secures the high-containment facility required to conduct the pivotal Marburg study.
Q4 CY25	Galidesivir	Establish Advisory Committee	Appointment of strategic advisors to guide the FDA Animal Rule process.
Q4 CY25	Corporate	US Government Engagement	Advance discussions for non-dilutive funding (grants) and procurement.
Q1 CY26	Galidesivir	Final FDA Feedback	Receipt of FDA comments on the proposed NHP study protocol.
Q1 CY26	Galidesivir	Start of Pivotal NHP Study	Commencement of the confirmatory animal study; the key de-risking event for the program.
Q2 CY26	**Galidesivir**	**Pivotal NHP Data Readout**	**MAJOR CATALYST. Confirmation of survival benefit (aiming to replicate historical ~94% survival).**
2H CY26	Galidesivir	NDA Submission	Submission of New Drug Application to the FDA under the Animal Rule.
Q1 CY27	**Galidesivir**	**FDA Approval & PRV Award**	**Potential FDA approval triggers the award of the Priority Review Voucher.**
Q1 CY27	**Galidesivir**	**PRV Monetization**	**Estimated sale of PRV (Modelled: US$140m gross / ~$105m net to ILA).**
Q1 CY27	**Galidesivir**	**Initial SNS Contract**	**Potential execution of initial stockpile procurement contract (Modelled: US$100m upfront).**
2028+	Galidesivir	Recurring SNS Revenue	Potential exercise of follow-on options for stockpile replenishment.
2027+	ISLA-101	Phase 3 / Field Studies	Potential progression of Dengue program into larger efficacy trials.

Galidesivir: De-Risked Biodefense Platform

Molecule Profile

Galidesivir is a broad-spectrum antiviral that mimics a natural building block of viral RNA, acting as a decoy that tricks the virus's replication machinery into halting the production of new viral genetic material. It is essentially a modified version of adenosine (one of the fundamental components of RNA), so when the viral enzyme mistakenly inserts Galidesivir in place of the real molecule, the RNA chain stops growing and the virus can't make new copies of itself. Because this approach targets a process common to many viruses, Galidesivir has demonstrated activity against numerous high-threat pathogens – including Marburg virus and its relative, Ebola – making it a promising defense against deadly outbreaks.

Development History

A pivotal element of the Island Pharmaceuticals investment case is the substantial leverage gained from historical investment. Galidesivir was originally discovered by BioCryst Pharmaceuticals and developed with extensive support from US government agencies, specifically the National Institute of Allergy and Infectious Diseases (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA).

To date, the program has benefitted from over US$70 million in non-dilutive government funding. This capital was deployed to generate a comprehensive Investigational New Drug (IND) package, which Island has now acquired.

Acquisition Rationale: Strategic Arbitrage

Investors may scrutinize why BioCryst, a Nasdaq-listed commercial biotech with a market capitalization exceeding US$1 billion, would divest an asset with such significant sunk costs. This divestment was driven by a strategic pivot rather than asset failure. BioCryst has reoriented its entire corporate structure to focus on its commercial rare disease franchise, specifically ORLADEYO for hereditary angioedema (HAE), and has deprioritized its anti-infective pipeline.

Island executed the acquisition of Galidesivir in July 2025 under highly favourable terms. The transaction structure includes an upfront Payment of US$500,000; contingent milestone payments payments tied to success, including US$1.5 million upon FDA approval under the Animal Rule; and a tiered royalty structure of 5-10% on net sales.

By acquiring a program with >US$70 million in development history for an upfront cost of US$500,000, Island has opened the door to exceptional return on invested capital (ROIC) potential. The company has effectively bypassed the high-risk, high-attrition discovery and preclinical phases, entering the development curve at a mature stage where the primary risks are regulatory execution rather than biological viability.

Global market Opportunity for Galidesivir

Marburg virus disease (MVD) is a rare but extremely lethal haemorrhagic fever, closely related to Ebola. Historically, fewer than 600 cases have been reported globally since the virus's discovery in 1967. Yet outbreaks, though sporadic, have been devastating: for example, the 2004-05 Angola outbreak infected 374 people and killed 329. Average case fatality is around 50%, underscoring the virus's deadly nature. Transmission occurs through contact with infected bats or bodily fluids of patients, and Marburg is not airborne, which typically limits the size of outbreaks geographically to parts of sub-Saharan Africa. Nevertheless, outbreaks have appeared across East, Central, and West Africa, including Uganda, DRC, Angola, and more recently Guinea, Ghana, Equatorial Guinea, Tanzania, and Rwanda. The widening geographic reach highlights a persistent risk of sudden outbreaks in regions with Rousettus bat populations (the natural reservoir) and the potential for cases exported internationally via travel.

Current Ethiopian Outbreak

Ongoing surveillance confirms that Marburg remains an active threat rather than a purely historical curiosity. In November 2025, Ethiopia's Ministry of Health declared the country's first Marburg outbreak, centred in the South Ethiopia and Sidama regions. As of the US CDC's 3 December 2025 situation update, 13 laboratory-confirmed cases had been identified and eight patients had died, with additional suspected infections still being evaluated. While no related cases have been reported in neighbouring countries or the United States and CDC currently assesses the risk to US residents as low, the episode demonstrates how a nation with no prior Marburg history but with the known bat reservoir can experience a sudden, lethal cluster. For investors, this reinforces the likelihood that major governments and global health funders will continue to prioritise procurement of Marburg countermeasures such as Galidesivir once an approved option exists.

Response & Treatment

Containing Marburg outbreaks is exceptionally challenging. Early symptoms mimic common tropical illnesses (malaria, typhoid, etc.), causing diagnostic delays. Outbreaks often occur in remote or resource-limited settings, straining local health systems. Strict infection control (PPE, patient isolation, safe burials) is required to stop spread, but implementing these measures quickly on the ground is difficult. Healthcare workers have frequently been infected during outbreaks when proper precautions falter. Cultural practices such as traditional burial rites further complicate containment.

Crucially, there are no approved vaccines or antiviral treatments for Marburg today. Developing a Marburg therapeutic or prophylactic (e.g. post-exposure) could drastically improve patient survival and help break chains of transmission. For instance, in Ebola, the introduction of monoclonal antibody treatments cut case fatality from ~70% to ~34% in trials, transforming outbreak management. A similarly effective Marburg drug could be used to treat confirmed cases and potentially as prophylaxis for high-risk contacts, containing outbreaks faster and protecting healthcare workers.

The Strategic National Stockpile Market

The Market for Marburg is unique, driven by government preparedness and outbreak-response needs rather than routine commercial demand. In the absence of endemic infection, the TAM is defined by biosecurity stockpiling and emergency outbreak stock. The US Strategic National Stockpile (SNS) is the nation's repository of antibiotics, vaccines, chemical antidotes, and other critical medical supplies. The SNS is mandated to hold countermeasures against high-priority threats. Marburg virus is classified as a Tier 1 Select Agent and a Category A Bioterrorism Agent, the highest level of threat classification, shared by Anthrax and Smallpox.

Despite this high classification, there are no FDA-approved treatments or vaccines for Marburg virus in the SNS. The US government has invested over US$600 million in grants attempting to close this gap, yet a viable approved product remains elusive. If Galidesivir secures FDA approval, it would become the only approved therapeutic for Marburg, granting it a monopoly position for SNS procurement.

SNS Key Involvements

The SNS is maintained by the Administration for Strategic Preparedness and Response (ASPR), part of the US Department of Health and Human Services (HHS). Operational management is carried out through the ASPR but was formerly managed by the CDC until it was transferred in 2018. The group is responsible for procuring, storing, and deploying vaccines, antibiotics, antivirals, antitoxins, chemical antidotes, PPE, ventilators, and other critical medical countermeasures for national emergencies.

BARDA is the Biomedical Advanced Research and Development Authority, a division within ASPR. BARDA is the key funding and procurement agency. Its mandate is to fund late-stage development of medical countermeasures; bridge the funding gap between early R&D and full commercial readiness; run advanced deployment, manufacturing

and procurement programs; and support regulatory approval. BARDA funds and advances products to the point where they can be purchased for the SNS.

Contract Economics

Contracts for biodefense assets are lucrative and often recurring, with the US government demonstrating a willingness to commit substantial capital to secure medical countermeasures against high-priority threats. Notable precedents include Emergent BioSolutions' BioThrax (anthrax), which secured a 5-year contract valued at up to US$911 million, following a prior US$1.25 billion procurement. Similarly, SIGA Technologies' TPOXX (smallpox) was awarded an initial US$472 million contract, followed by a US$629 million extension, highlighting the long-tail revenue potential of these assets. More recently, Chimerix (now Emergent) received a US$680 million contract for Tembexa (smallpox), while Bavarian Nordic has secured over US$500 million for its Jynneos vaccine. These examples underscore a clear market framework where FDA-approved biodefense assets, particularly those approved via the Animal Rule, can rapidly secure multi-hundred-million-dollar stockpile agreements. The table below compiles major products in the SNS.

Figure 1: Major US Strategic National Stockpile (SNS) countermeasures and associated BARDA/CDC procurement contracts, illustrating the multi-hundred-million-dollar commercial framework for FDA-approved biodefense products. Various Sources.Wri

Product (Threat)	Developer / Contractor	SNS Contracts
BioThrax (Anthrax)	Emergent BioSolutions	5-year CDC supply contract (2016-2021) for ~29.4 million doses to SNS, valued up to $911 million (avg. circa ~$31/dose). A prior 5-year contract delivered ~44.8 million doses for ~$1.25 billion. In 2017, BARDA added a $100 million order for additional BioThrax doses.
NuThrax – Next-gen Anthrax Vaccine	Emergent Biosolutions	Project BioShield BARDA contract (2016) for advanced development and procurement of NuThrax, valued at $1.6 billion (base and options). This supports FDA approval and future SNS deliveries (up to 50 million doses).
ABthrax – Anthrax Monoclonal Antitoxin	Human Genome Sciences / GSK / now Emergent	Initial SNS procurement (2009) of 65,000 doses delivered under contracts totalling $151 million. BARDA contract (2013) for 60,000 doses over 4 years for ~$196 million. Emergent acquired ABthrax in 2017, assuming a remaining BARDA contract (~$130m) to complete SNS deliveries.
Anthim – Anthrax Monoclonal Antitoxin	Elusys Therapeutics (acquired by NightHawk Bio)	BARDA procurement contract (2015) with initial order of Anthim for SNS worth $44.9m. Elusys received over $240m in US government grants/contracts (DoD, NIH, BARDA) to develop Anthim.
ACAM2000 (Smallpox)	Acambis / Sanofi (now Emergent)	CDC 10-year contract (2008-2018) supply of ~180 million doses, base value $425m. Options allowed up to 39 million additional doses in years 5-10 (total contract up to $660m). Prior to FDA approval (2007), CDC had already purchased ~195 million doses at ~$1.95/dose (~$380m total) for the stockpile. Emergent acquired ACAM2000 from Sanofi in 2017, with ~$160m contract value remaining.
Jynneos (Smallpox / Monkeypox)	Bavarian Nordic A/S	BARDA freeze-dried vaccine contract (2017-2027) 10-year base contract including a $299m option for producing freeze-dried Jynneos. The first option segment of $119m was awarded in 2022. After the 2022 mpox outbreak (which drew down stockpile), BARDA issued new orders to replenish supply: $120m in 2023 (bulk vaccine for ~13m doses, initiating freeze-dried production in 2024), and an additional $63m in late 2024 for more bulk and ~1 million freeze-dried doses (deliveries in 2025-26). In total, Bavarian Nordic has received well over $500m for Jynneos from the US, and had supplied ~30 M liquid-frozen doses under earlier contracts.
TPOXX (Smallpox)	SIGA	Project BioShield BARDA contract (2011) initial procurement of ~1.7 million courses for the SNS (contract ~$472m; completed by 2017). BARDA follow-on contract (2018) valued up to $629m to maintain ~1.7 million courses in the stockpile and develop IV TPOXX. This 5-year base + options covers ~$52m base (incl. 35,700 courses) and ~$577m in options (for up to 1.45m additional courses, IV formulation

		procurement, post-market studies, etc.). As of 2022, BARDA exercised options for additional IV doses (~$26m).
Tembexa (Smallpox)	Chimerix (rights sold to Emergent in 2022)	BARDA procurement contract (2022) up to $680 million over 10 years to supply up to 1.7 million courses of Tembexa to the SNS. Initial BARDA order: $115m for ~319,000 courses; plus up to $551m in options for remaining courses + $13m for post-marketing commitments. Upon this award, Emergent acquired Tembexa for $225m upfront, with Chimerix eligible for up to $124m in milestones tied to option exercises.
Imnazeb (Ebola)	Regeneron	BARDA provided extensive R&D funding and a 6-year procurement commitment for Inmazeb. In total, Regeneron received over $700m via two BARDA contracts (for development and set purchases of Inmazeb).
Heptavalent Botulism Antitoxin (Botulism)	Cangene (acq. By Emergent)	BARDA base contract (2006) supported development and SNS stockpiling (value unknown). Multiple modifications/options have followed: e.g. a $53m BARDA contract mod in 2015 for manufacturing and a $62.4m ASPR contract modification in 2023 to replenish stockpile supply.
DuoDote (Nerve Agents)	Meridian Medical Technologies	ASPR/SNS contract (2025) valued up to $129m to supply DuoDote autoinjectors for nerve-agent preparedness. (Contract includes a one-year base and option years for sustained stockpile maintenance.) DuoDote is FDA-approved for treatment of organophosphate nerve agent poisoning and is stockpiled via the CHEMPACK program.
G-CSF Therapies e.g. Neupogen, Neulasta (Radiation, Acute Radiation Exposure (ARS))	Amgen, Sanofi	Project BioShield procurements (2013-2016) – HHS used BioShield funds to acquire colony-stimulating factors for radiological emergencies. In 2013, HHS purchased 541,000 doses of Neupogen for $157m. In 2016, BARDA bought $37.7m of Neulasta (Amgen) and $37.6m of Leukine (Sanofi). These agents, originally cancer drugs, were approved/used under the Animal Rule for ARS and promptly stockpiled to improve survival after radiation exposure.

TAM

Precise TAM figures are difficult to quantify for such a sporadic disease, but analogies provide a framework. If the US were to secure on the order of ~50,000 treatment courses for its stockpile (enough to tackle a moderate outbreak or bioterror incident), at an estimated cost of $2,000 to $5,000 per course (typical for complex antivirals/biologics), that alone would represent a US$100–250 million opportunity. Globally, adding in other nations and international stockpiles could roughly double that. In total, a plausible addressable market could reach a few hundred million dollars in procurement value, concentrated in initial government stockpile contracts and replenishment over time.

Commercial Architecture: Priority Review Voucher

The Tropical Disease Priority Review Voucher (PRV) program is a regulatory incentive created by Congress (FDAAA 2007) to spur development of treatments for neglected diseases. Upon approval of a qualifying drug, the sponsor receives a voucher that entitles the holder to an expedited 6-month FDA review for any future drug application. Because this acceleration can pull forward hundreds of millions of dollars in revenue for a blockbuster drug, big pharmaceutical companies are willing to pay significant sums to acquire these vouchers on the secondary market.

The secondary market for PRVs is active and provides transparent pricing benchmarks. Recent transactions in 2024 and 2025 confirm the asset's high value:

- Bavarian Nordic: Sold a Tropical Disease PRV for US$160 million in 2024.
- Ipsen: Sold a Rare Paediatric Disease PRV for US$158 million in August 2024.
- PTC Therapeutics: Entered an agreement to sell a PRV for US$150 million.

- Valneva: Sold a Tropical Disease PRV for US$103 million in early 2024.

Importantly, no extra, separate, post FDA-approval application is needed for a tropical disease PRV. However, it's award is not automatic for every tropical disease approval: the voucher is only provided if the NDA/BLA both (i) meets the statutory criteria, and (ii) included a PRV request and supporting justification in the original submission. If these conditions are met, the voucher is awarded in the approval letter itself.

To qualify under the statutory criteria, the application must:

i. Be an NDA or BLA under 505(b)(1) FD&C Act or 351 PHS Act.

ii. Be for prevention or treatment of a listed tropical disease.

iii. Qualify for priority review on its own merits (serious condition + meaningful improvement vs existing options).

iv. Contain no previously approved active ingredient (no active moiety that has been approved in any other 505(b)(1) NDA or 351 BLA).

v. Include one or more new clinical investigations (other than BA/BE) that are essential to approval and were funded/sponsored by the applicant.

Unique & Expedited Regulatory Pathway

Mechanics of 21 CFR 314.600

The FDA's Animal Rule is a specialized regulatory pathway established in 2002 to facilitate the approval of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats. It addresses a critical ethical dilemma: it is impossible to conduct traditional Phase 3 efficacy trials for high-mortality threats like Marburg because it would be unethical to deliberately expose healthy volunteers to the pathogen, and natural outbreaks are too sporadic and geographically remote to support large-scale field trials.

Under the Animal Rule (21 CFR 314.600 for drugs), the FDA grants approval based on efficacy data derived from adequate and well-controlled animal studies, provided that safety is established in humans. To utilize this pathway, a sponsor must satisfy four rigorous criteria:

1. **Mechanism of Toxicity:** The pathophysiological mechanism of the threat agent's toxicity and the drug's prevention of that toxicity must be reasonably well-understood.

2. **Predictive Efficacy:** The effect must be demonstrated in more than one animal species expected to predict human response, unless a single animal species is a sufficiently well-characterized model for predicting human response.

3. **Endpoint Correlation:** The animal study endpoint must be clearly related to the desired benefit in humans (typically survival).

4. **PK/PD Bridging:** The data must allow for the selection of an effective dose in humans based on pharmacokinetic (PK) and pharmacodynamic (PD) bridging.

Regulatory Alignment and De-Risking

A major de-risking event for Island Pharmaceuticals occurred in November 2025, when the company received formal written feedback from the FDA following a Type C meeting request. The regulator explicitly confirmed two critical points: (i) the Animal Rule is the appropriate and viable regulatory pathway for the development of Galidesivir

as a countermeasure against Marburg virus disease; and (ii) Galidesivir would qualify for a Tropical Disease Priority Review Voucher (PRV) upon approval.

This regulatory alignment is significant. It confirms that Island does not need to plan for complex, multi-year human efficacy trials. Instead, the critical path to approval runs through a confirmatory Non-Human Primate (NHP) study.

Historical Precedents

A comparative analysis of previous Animal Rule approvals illustrates the potential trajectory for Galidesivir:

Product	Indication	Sponsor	Approval	Commercial Outcome
TPOXX (tecovirimat)	Smallpox	SIGA Technologies	2018	Secured >US$1 billion in SNS and international contracts; recent orders of ~US$113m in 2024.
Tembexa (brincidofovir)	Smallpox	Chimerix / Emergent	2021	Secured BARDA contract valued up to US$680 million; initial procurement of US$115 million.
Raxibacumab (ABthrax)	Anthrax	GSK / Emergent	2012	Initial $151m SNS contract in 2009 followed by 2013 $196m BARDA follow-on contract.

These precedents underscore a recurring pattern: FDA approval under the Animal Rule acts as a trigger event for substantial, long-term procurement contracts from the US government. By targeting Marburg, the only Category A filovirus without an approved therapeutic, Island is positioning Galidesivir to replicate the commercial success of TPOXX and Tembexa.

Strategic Government Engagement

To navigate the complex federal procurement landscape, Island has appointed Todd Strategy Group (TSG). TSG is a specialist consultancy staffed by former senior officials from BARDA and ASPR. Island's lead principal at TSG is Taylor Sexton, a former Senior Advisor to the ASPR who was instrumental in Operation Warp Speed.

This appointment signals a sophisticated approach to government relations. TSG's mandate is twofold: (i) secure non-dilutive funding (inc. identifying and securing government grants) which would protect shareholder equity); (ii) negotiate procurement and position Galidesivir for an advance purchase agreement or SNS contract concurrent with FDA approval.

Scientific Validation: Analysing the Data Package

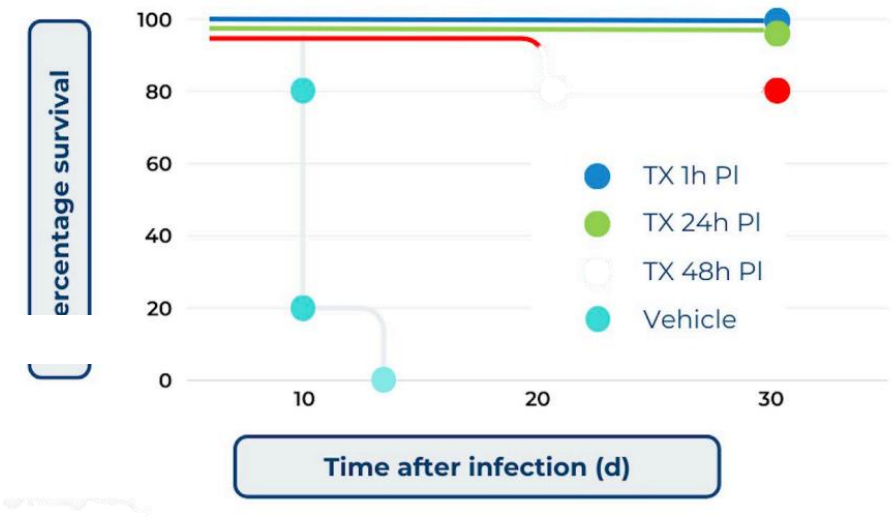
NHP Efficacy in Filovirus Models (Marburg & Ebola)

Marburg

In a pivotal study by BioCryst, Galidesivir (BCX4430) demonstrated robust protection in cynomolgus macaques challenged with Marburg virus. All six untreated control animals succumbed by ~10 days post-infection, whereas 17 of 18 Galidesivir-treated monkeys survived (~94% overall survival). Survival depended on how soon treatment began after exposure. Notably, 5 of 6 monkeys (83%) survived when dosing started 1 hour post-infection, and 6 of 6 (100%) survived when treatment was initiated at 24 or 48 hours post-infection. All treated groups showed significantly improved survival versus placebo (log-rank $p < 0.01$) with no obvious drug-related toxicity observed at the effective dose (15 mg/kg intramuscular (IM) twice daily for 14 days). These findings indicate Galidesivir's

broad therapeutic window in Marburg infection, a rare attribute among filovirus antivirals.

Figure 2: Figure 1: Survival of Marburg virus–infected non-human primates treated with galidesivir. Source: Island Pharmaceuticals investor presentation, p.9.

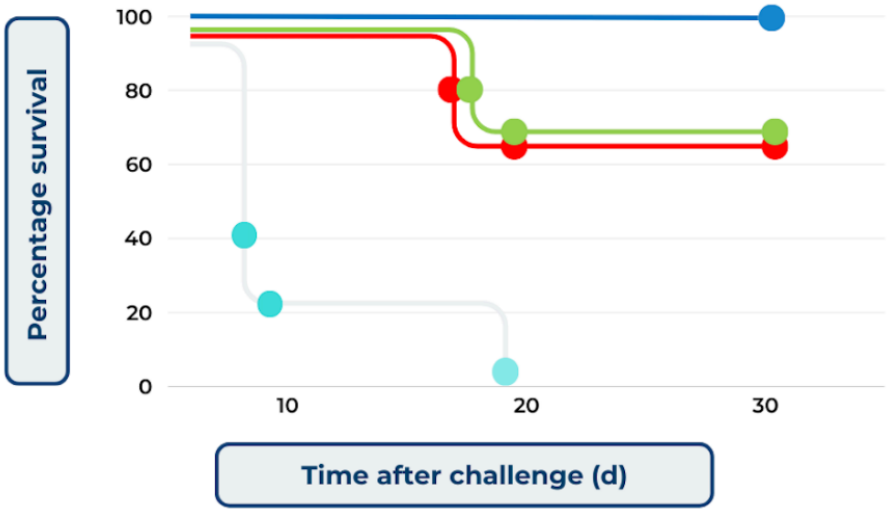


The 100% survival rate when treatment is delayed by 48 hours is clinically significant. In a bioterrorism event or a natural outbreak in a resource-poor setting, immediate treatment is logistically impossible. A therapeutic window of 48 hours provides sufficient time to identify and treat exposed individuals (e.g. military personnel, first responders) with a high probability of preventing mortality. This "post-exposure prophylaxis" (PEP) capability is a highly sought-after attribute for the SNS.

Ebola

Follow-up NHP studies in Ebola virus disease (using rhesus macaques) corroborated Galidesivir's broad-spectrum filovirus activity. In an initial Ebola study, immediate post-exposure treatment (within ~1 hour) achieved 100% survival (6/6 monkeys). A second study tested delayed treatment onset: when Galidesivir administration began 48 hours after Ebola infection, all 6 of 6 monkeys survived (100%), and a 72-hour delay still protected 4 of 6 animals (~67% survival). By contrast, all control animals in these Ebola studies succumbed (0% survival). The survival benefit remained statistically significant even at the 72-hour start time ($p<0.05$). These results confirm that Galidesivir can rescue NHPs from lethal Ebola infection, especially when given within a 2-day post-exposure window

Figure 3: Ebola NHP survival following delayed galidesivir treatment. Source: *Island Pharmaceuticals presentation, p.11.*



Human Safety Profile

The safety database for Galidesivir is comprised of data from over 100 healthy human volunteers across Phase 1 trials. The drug was found to be generally safe and well-tolerated, with no serious adverse events (SAEs) reported.

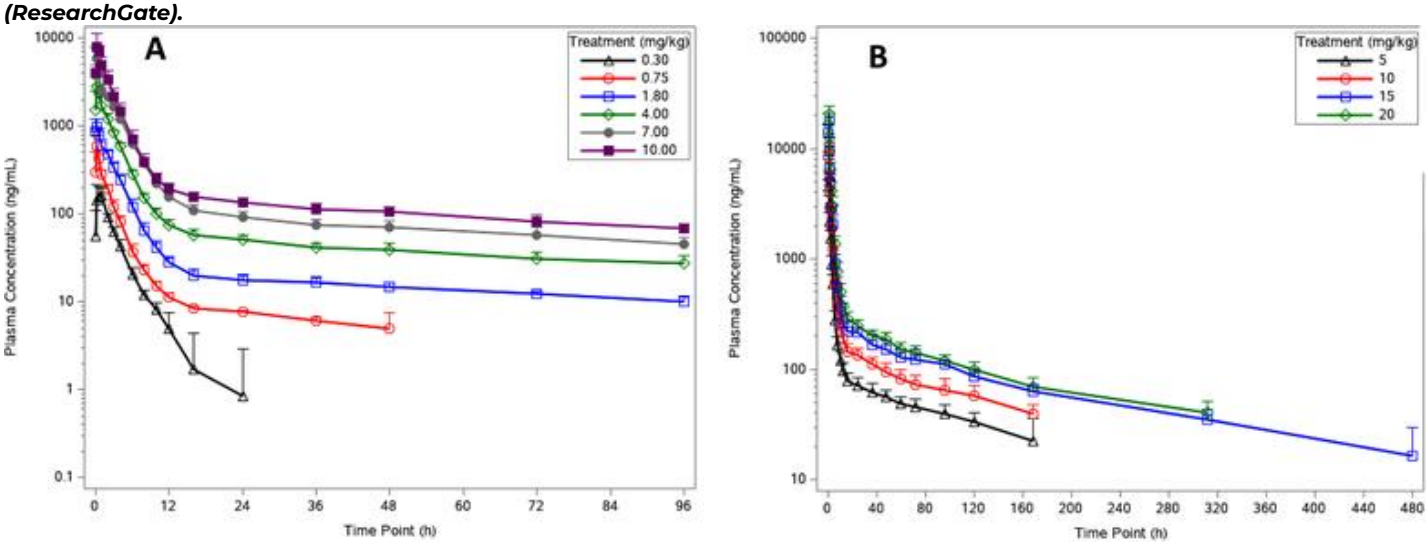
Critically, the Phase 1 program evaluated both Intravenous (IV) and Intramuscular (IM) administration routes.

- **IV Administration:** Standard for hospital-based treatment of severe cases.
- **IM Administration:** A strategic advantage for biodefense. In a field setting or mass casualty event, establishing IV lines is time-consuming and requires skilled personnel. An IM formulation allows for rapid "jab-and-go" deployment, like an EpiPen or vaccine. This logistical flexibility offers a distinct competitive advantage over therapeutics that are strictly IV-only, such as Remdesivir.

Pharmacokinetic Profile

After IM injection (left graph below), Galidesivir is rapidly absorbed (reaching peak plasma levels quickly) and exhibits a biphasic elimination curve. Specifically, a fast distribution phase is followed by an extended terminal half-life phase, indicating prolonged exposure of the drug even after initial clearance. This PK profile was similar for IV infusion (right graph below), with 60-minute IV dosing (5-20 mg/kg) producing a comparable two-phase plasma concentration–time profile. The extended half-life supports twice-daily dosing, as employed in the animal studies.

Figure 4: Plasma concentration–time profiles of galidesivir in healthy adults following single (A) and multiple (B) intravenous dosing across a range of dose levels, demonstrating rapid distribution and dose-dependent systemic exposure. Source: *Pharmacokinetics and Safety of the Nucleoside Analog Antiviral Drug Galidesivir Administered to Healthy Adult Subjects (ResearchGate).*



Taken together, the human PK/safety data suggest that efficacious exposures (like those in NHP models) are achievable via IM dosing without significant toxicity. This de-risks Galidesivir's development under the FDA Animal Rule: the drug has demonstrated replicable survival benefits in two relevant animal models (Marburg and Ebola NHPs) and has clinical Phase 1 evidence of safety and deployability via intramuscular injection.

Competitive Landscape

The Marburg therapeutic landscape is sparse, reflecting the difficulty of development and the specialized nature of the market. Though, there exists direct competition from major big pharma:

Competitor	Asset	Class	Status	Limitations
Gilead	Remdesivir	Nucleoside Analogue	Approved for Covid; NHP efficacy in Marburg	IV only therefore requiring infusion infrastructure and cold chain. Logistically difficult to deploy.
Mapp Biopharmaceutical	MBP091	Monoclonal Antibody	Phase 1 Development	Strain specific to Marburg, lacking broad-spectrum utility; expensive to manufacture; requires cold chain.

Galidesivir has a competitive moat:

i. **Small molecule stability:** unlike antibodies or mRNA vaccines, small molecules are generally more stable and easier to stockpile logistically.

ii. **Broad spectrum utility:** it's efficacy against Ebola and other viruses adds value to the stockpile, as it could theoretically be deployed in multiple outbreak scenarios.

iii. **IM administration:** the existence of an intramuscular formulation is a critical differentiator. In a biodefense context, the ability to rapidly administer a drug via injection (without establishing an IV line) allows for mass treatment of exposed populations by non-specialized personnel. This logistical flexibility is often a decisive factor in SNS procurement decisions.

ISLA-101: Repurposed Dengue Antiviral Program

While Galidesivir underpins Island's near-term Marburg biodefense opportunity, the company also owns ISLA-101, an oral antiviral being repurposed for dengue that leverages an established human safety record and early proof-of-concept in a controlled dengue challenge model. This legacy program provides a second, more traditional infectious disease asset with exposure to large endemic and travel markets, complementing the binary, government-driven economics of Galidesivir. The following section outlines the unmet need in dengue, the size of the commercial opportunity, and how ISLA-101 could contribute to Island's longer-term growth profile beyond the Marburg indication.

Critical Unmet Need in Dengue Prevention & Treatment

Dengue fever represents a major unmet medical need globally. There are currently no specific antiviral treatments approved for dengue and care is limited to symptom management (e.g. fluids, fever/pain relief, hospital support for severe cases). On the preventative side, vaccines have had limited impact. The only approved dengue vaccine (Sanofi's Dengvaxia®, first approved 2015) is restricted in use due to safety issues: it provides good protection only in individuals with prior dengue exposure but can increase risk of severe dengue in those never infected before. Accordingly, health authorities recommend vaccinating only seropositive patients of certain ages, and Dengvaxia uptake has been extremely low (sales fell from €55 million in 2016 to just €3 million in 2017). New tetravalent vaccines (e.g. Takeda's TAK-003/Qdenga) are in development and starting to reach markets, but questions remain about their efficacy in dengue-naïve populations and long-term safety. In summary, no widely effective prophylactic or therapeutic options exist today, underscoring a critical need for novel dengue interventions.

Global Dengue Market Opportunity

The dengue disease burden has escalated dramatically, creating a large potential market for dengue antivirals or prophylactics. Globally, reported dengue cases swelled from about 505,000 in 2000 to 14.6 million in 2024. In 2024 dengue hit a historic peak with 14.6 million cases and over 12,000 deaths reported across 100+ countries. Actual infections are far higher when including asymptomatic cases, in the order of 390 million infections annually. Roughly half of the world's population lives at risk in dengue-endemic regions, primarily in Asia, Latin America, and Africa. Urbanisation and travel are further expanding dengue's range, evidenced by recent outbreaks in previously unaffected areas: In 2024, 308 cases were reported to WHO from three European countries (France, Italy and Spain) and an additional 1291 cases and four deaths were recorded in the French overseas territories of Mayotte and Réunion.

Total Addressable Market

The growing prevalence translates into a substantial addressable market for dengue therapeutics. A 2013 University of Washington analysis estimated ~58.4 million symptomatic dengue cases per year (causing ~13,600 deaths) and an economic burden ~US$8.9 billion annually in direct and indirect costs. The TAM can be framed in multiple segments:

- **Endemic country healthcare systems:** Hospitals and public health programs in dengue-endemic nations would benefit from a treatment that reduces disease severity or a prophylactic to protect high-risk groups. Given tens of millions of cases each year, even a modestly priced antiviral could see high volume in these regions, though affordability and public funding are key considerations.

- **Travel medicine market:** Millions of international travellers visit dengue-endemic areas annually for tourism, business, and education. This segment mirrors the malaria prophylaxis market: travellers and expatriates may opt for a dengue preventive pill if available. For perspective, the US reported over 7,500 travel-related dengue cases in 2010-2021, and many more infections likely go unreported. A safe, oral prophylactic like ISLA-101 could be prescribed pre-trip to mitigate dengue risk, representing a lucrative private-pay market.

- **Military and governmental use:** Dengue has long afflicted military personnel in tropical deployments. Protecting troops is a priority: the US Army, for example, maintains a Dengue Human Infection Model and has been actively researching countermeasures. At any time, over 160,000 US active-duty service members are stationed overseas (many in dengue regions). Armed forces and government agencies could be significant customers for a prophylactic drug to safeguard personnel and aid workers in endemic areas, potentially via bulk procurement or stockpiling contracts (analogous to how militaries stockpile malaria drugs or how governments purchase vaccines).

In sum, a successful dengue antiviral/prophylactic could address a large global patient population and multiple high-value segments. The serviceable market would include not only those acutely ill with dengue (to receive therapeutic treatment), but also healthy individuals in endemic regions or travellers (to receive prophylaxis).

ISLA-101 MOA & Development History

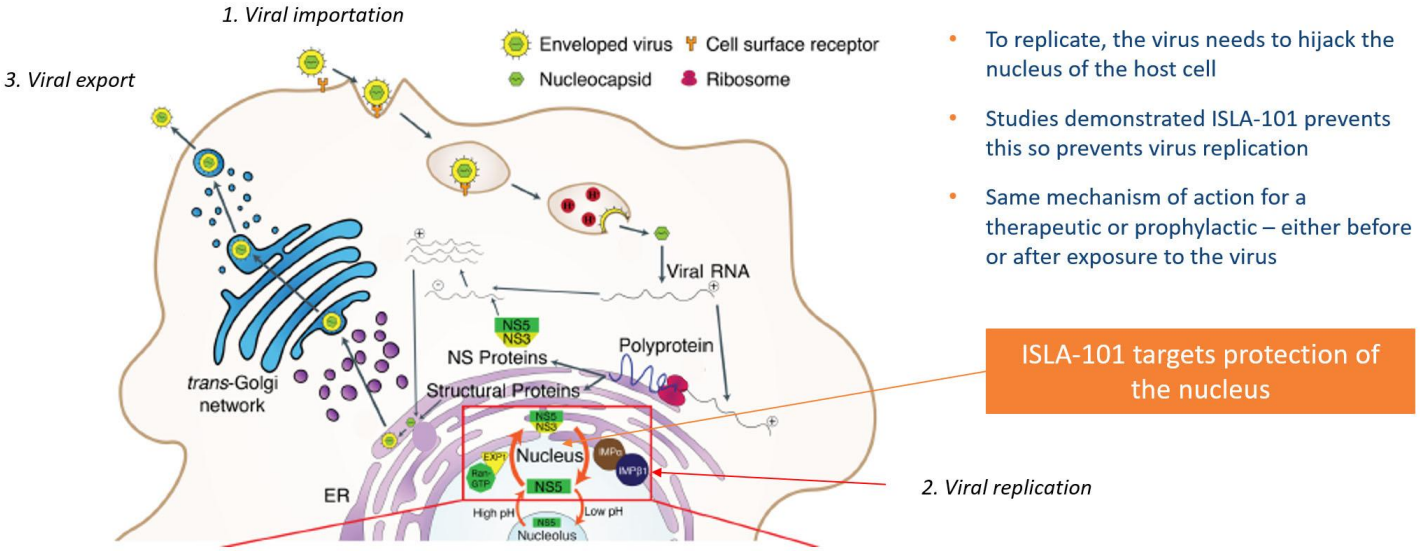
Mechanism of Action

ISLA-101 is an oral formulation of fenretinide, a synthetic retinoid derivative that has shown potent antiviral activity against dengue and other flaviviruses. Unlike typical antivirals that directly target viral proteins, fenretinide exerts a host-targeted mechanism that disrupts the dengue virus's replication process. It limits the accumulation of viral RNA inside infected cells, dramatically reducing dengue viral replication. It achieves this in part by interfering with the virus's ability to hijack host cell pathways: notably, fenretinide was identified in a high-throughput screen as an

inhibitor of the interaction between the dengue virus NS5 protein (a key viral enzyme) and host nuclear transport proteins. By blocking NS5 from entering the cell nucleus and disabling certain host factors, the drug prevents the virus from suppressing the host immune response and replicating efficiently.

Fenretinide also modulates cellular stress responses in a way that is inhospitable to the virus. It specifically activates the protein kinase R-like ER kinase (PERK) arm of the unfolded protein response (a cellular stress pathway). This stress response induction is thought to create an antiviral state in the cell. Importantly, these actions do not involve direct inhibition of the dengue polymerase or other viral enzymes. Instead, ISLA-101 effectively "turns on" host cell defences and shuts down the environment needed for viral genome replication. The outcome is a marked drop in viral load and curtailed infection. Fenretinide's antiviral effect has been observed against all four dengue serotypes, including in scenarios of antibody-dependent enhancement (where pre-existing dengue antibodies worsen infection. This broad mechanism suggests a high barrier to resistance and applicability against dengue's variants.

Figure 5: Mechanistic illustration of ISLA-101's antiviral action: the drug blocks viral access to, and hijacking of, the host cell nucleus, thereby preventing replication and subsequent viral export. This nucleus-protective mechanism supports both therapeutic and prophylactic use. *Source: Island Pharmaceuticals website.*



Development History

Originally investigated in the 1980s and 1990s as an anti-cancer and chemopreventive agent, fenretinide was studied in dozens of clinical trials (enrolling thousands of patients) for various cancers – including breast cancer, lung cancer, and childhood neuroblastoma – because of its pro-apoptotic and low-toxicity profile. While it showed a favourable safety/tolerability profile and some efficacy signals in oncology, fenretinide never achieved regulatory approval for cancer.

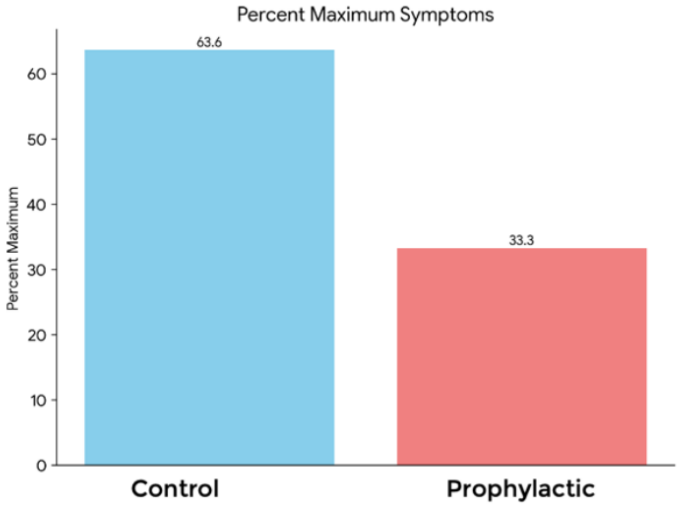
The opportunity in dengue emerged from academic research in the 2010s. In 2014, a Monash University-led team (Fraser et al.) discovered fenretinide's antiviral potential via a screen for inhibitors of dengue NS5-host interactions. They found fenretinide protected mice from lethal dengue infection (in an antibody-enhanced disease model) – mice treated with fenretinide had significantly improved survival compared to controls. Around the same time, studies at Harvard demonstrated fenretinide's activity against dengue in cell culture and its ability to suppress Zika virus in mice.

Island Pharmaceuticals was founded to capitalize on this opportunity. The company acquired exclusive rights and intellectual property to fenretinide's use in dengue and other mosquito-borne viruses. By repurposing a known drug, Island could leapfrog early-stage risks – fenretinide already had an established safety record in humans, de-risking Phase 1 development. Island formulated the drug in a capsule suitable for antiviral dosing (branded ISLA-101) and pursued additional patents (new use patents now extend IP protection into the 2030s for ISLA-101 in arboviral diseases.

Recent Clinical Developments

In 2022-2023, Island opened an IND for ISLA-101 and moved directly into a Phase 2 human trial. The Phase 2 program – dubbed PROTECT – was designed as a two-part study using a controlled human infection model for dengue. In collaboration with the US Army Medical Research team, Island tested ISLA-101 in healthy volunteers who were deliberately exposed to a weakened strain of dengue virus under clinical supervision. The Phase 2a (preventative) arm evaluated ISLA-101 as a prophylaxis: volunteers took ISLA-101 or placebo 3 days before being inoculated with the virus. The trial read out in late 2024 showed positive results: ISLA-101 was found to be safe and met key antiviral efficacy benchmarks, such as achieving target drug levels and showing reduced viremia (viral load) in treated subjects compared to controls. Re symptoms, the control group reported ~64% of all potential symptoms (of max number of recorded symptoms relating to Dengue Fever), compared to ISLA-101 pre-treated subjects reporting ~33%. Those dosed with ISLA-101 as a prophylactic were less sick that those that received the placebo.

Figure 6: Reduction in dengue symptom burden in the Phase 2a preventative cohort, with ISLA-101 pre-treated subjects reporting ~33% of maximum symptoms versus ~63% in controls. Source: Island Pharmaceuticals ASX announcement 12/06/2025, p.2.



Following a safety review confirming no significant issues, the trial progressed to the Phase 2b (treatment) arm in early 2025. In Phase 2b, participants were first infected with the dengue challenge virus, then treated with ISLA-101 to see if it could mitigate symptoms and viral levels post-infection. Island successfully completed dosing of 10 subjects in this Phase 2b cohort by February 2025. The Company stated in the June reading of results that ISLA-101 impacted viral replication but because some subjects were viremic and symptomatic at the time of first dosing, alterations in symptoms were less pronounced and are being investigated further. No update has since been provided.

Future plans for ISLA-101 will likely involve more expansive field trials: for example, a Phase 3 trial in dengue-endemic regions or among travellers to evaluate real-world protective efficacy, and/or a trial in dengue patients to confirm clinical benefit in treating active infections. Additionally, the broad-spectrum antiviral activity of fenretinide opens the door to targeting other arboviruses – Island has noted potential to apply ISLA-101 to diseases like Zika, West Nile, Japanese encephalitis, and chikungunya, which could further expand the market and value of this asset

Financial Analysis & Corporate Structure

Island maintains a rather lean operating structure, burning relatively little cash. Net cash used in operating activities for Q1 FY26 was $820k, largely attributable to R&D and administrative costs ($364k and $378k, respectively). The Company spent $845k on intellectual property (investing activities). On 30 September 2025, ILA had $6.9m cash. With the exercise of all ~14.4m ILAAP options, the Company's pro-forma cash balance equals $7.9m.

After the exercise of all ILAAP $0.07 options on 3 December 2025, the Company now has 269,052,397 shares on issue and a further 29,304,803 options outstanding. All options are ITM.

ASX Code	Expiry Date	Exercise Price	Number on Issue	Ex. Value
ILAAM	28-Apr-2026	$0.21	1,380,000	$289,800
ILAAQ	04-Dec-2026	$0.07	19,428,969	$1,360,028
ILAAO	21-Mar-2027	$0.12	1,895,834	$227,500
ILAAL	Various	Various	6,600,000	N/A
TOTAL			29,304,803	$1,877,328

Cost of Remaining Development

The primary remaining cost is the pivotal NHP study. Costs for GLP-compliant studies in BSL-4 facilities typically range from US$3 million to US$6 million, depending on the number of animals and study duration. While Island has sufficient cash to fund this study internally, the engagement of TSG suggests a strategic intent to secure non-dilutive funding (BARDA/NIAID grants) to cover these costs. If successful, this would further enhance the return on equity for shareholders. If not successful or should this process be delayed, the company may have to tap equity markets.

Valuation

Valuing Island Pharmaceuticals presents unique challenges distinct from traditional revenue-generating biotechs. The company's intrinsic value is heavily weighted towards binary regulatory and commercial events, specifically the receipt and subsequent sale of PPRVs the award of US SNS contracts, rather than steady-state cash flows. Given the unpredictability of timing and the 'all-or-nothing' nature of these catalysts, a traditional Discounted Cash Flow (DCF) analysis would rely on highly speculative terminal values and discount rates, potentially distorting the investment picture. Consequently, we have elected to forgo a standard DCF model in favour of a Sum-of-the-Parts (SOTP) framework. This methodology aggregates the risk-adjusted Net Present Value (rNPV) of the Galidesivir and Dengue programs, alongside current cash reserves and liquid regulatory assets, to derive a more representative valuation of the company's latent potential.

The SOTP framework yields an equity value of A$247.9m, resulting in a fair value per share of $0.83. This represents an 57% total shareholder return above the current price of $0.53.

	Asset Component	Gross Value (USD)	Royalties / Net (USD)	Probability of Success (PoS)	Timing (Est.)	Discount Factor (at 15% WACC)	rNPV (USD)	rNPV (AUD)	Contribution per Share
1)	Galidesivir PRV Sale	$140m	($35m) / $105m	65%	Q1 2027	0.84	$57.30	$88.2m	$0.30
2)	Initial SNS Contract	$100m	($10m) / $90m	65%	Q1 2027	0.84	$49.10	$75.6m	$0.25
3)	Follow-on SNS Options	$150m	($15m) / $135m	40%	2028-2030	0.65	$35.10	$54.0m	$0.18
4)	ISLA-101 Program	$120m	$120m	20%	2029	0.6	$14.40	$22.2m	$0.07
5)	Net Cash	A$6.90m	$6.90	100%	Current	1	A$6.90	$7.9m	$0.03
						Total Equity Value		**$247.9m**	**$0.83**

Galidesivir PRV Sale
We model a gross sale price of US$140m. Recent precedents in late 2024/2025 (e.g., Ipsen, PTC Therapeutics) have seen PRVs trade between US$150m–$160m. We apply a slight discount to be conservative. BioCryst is entitled to 25% of PRV proceeds. This is a hard contractual outflow, leaving ILA with ~$105m net. We assign a high PoS relative to standard biotech. The FDA has explicitly confirmed the Animal Rule pathway and PRV eligibility. With human safety (Phase 1) already established and strong NHP efficacy data (94-100% survival), the primary remaining hurdle is the confirmatory animal study, which is far less risky than a human efficacy trial.

Initial US SNS Contract
We assume a US$100m upfront procurement contract. This is conservative compared to precedents like SIGA's TPOXX (initial ~$472m) or Chimerix's Tembexa (~$115m initial + options). BioCryst holds a tiered royalty of 5-10% on net sales. We have modelled the upper band (10%). We align this with the PRV sale in early 2027, assuming a stockpile contract is signed concurrently with or immediately following FDA approval.

As for follow-on SNS Options, Government contracts typically include "vendor managed inventory" or replenishment options. We model a 3-year tail of US$50m/year starting in 2028. We risk this more heavily than the initial contract using a 40% PoS factor. While recurring revenue is common (e.g., Emergent's BioThrax), budget priorities change. This reflects the risk that the government buys a "one-off" stockpile and delays replenishment.

ISLA-101 Program
This asset is currently overshadowed by Galidesivir but holds significant latent value. We value it based on a future PRV potential ($100m net) plus modest endemic sales, but discount it heavily. We use a standard 20% Phase 2 PoS. While the Phase 2a prophylaxis data was positive, the program likely requires a larger field study or Phase 3 trial, which introduces higher clinical and execution risk than the Animal Rule pathway.

Currency & Shares
We apply an AUD/USD FX rate of 0.65 (constant through forecasted period) and a fully diluted share count of ~298m. This accounts for the ~29m options (largely ITM) being exercised, which effectively "pre-dilutes" the valuation but also assumes the cash from exercise (~A$1.9m) is added to the balance sheet.

Sensitivity Analysis

Our valuation is most exposed to assumptions around the Galidesivir PRV sale and the initial US SNS contract, with the base case of $0.83 per share sitting in the middle of wide, but still bounded, ranges. Varying the PRV sale price between US$100–180m and the probability of success between 45-85% shifts the implied value from about $0.68 at the low end (US$100m, 45% PoS) up to roughly $1.03 (US$180m, 85% PoS), underscoring how central PRV monetisation is to the thesis. Changes to the initial SNS contract are somewhat less dramatic but still material: across US$80-120m and 45-85% PoS, the valuation moves from roughly $0.72 to $0.97 per share. The follow-on SNS options mainly drive upside optionality, with outcomes ranging from about $0.71 (US$100m, 20% PoS) to $1.01 (US$200m, 60% PoS). By contrast, the ISLA-101 dengue program has a more modest impact, with the fair value price moving from around $0.76 (0% PoS) to at most $0.95 (40% PoS and US$160m value), illustrating that while dengue is a meaningful kicker, the core of the valuation rests on Galidesivir's PRV and SNS economics.

PRV Sale

PRV PoS	$0.83	$100m	$120m	$140m	$160m	$180m
	45%	0.68	0.71	0.74	0.77	0.80
	55%	0.71	0.75	0.79	0.82	0.86
	65%	0.75	0.79	0.83	0.87	0.92
	75%	0.78	0.83	0.88	0.92	0.97
	85%	0.81	0.87	0.92	0.98	1.03

Initial SNS Contract

SNS Contract PoS	$0.83	$80m	$90m	$100m	$110m	$120m
	45%	0.72	0.74	0.75	0.77	0.79
	55%	0.75	0.77	0.79	0.81	0.83
	65%	0.78	0.81	0.83	0.86	0.88
	75%	0.81	0.84	0.87	0.90	0.93
	85%	0.84	0.88	0.91	0.94	0.97

Follow-on SNS Options

Follow-on PoS	$0.83	$100m	$125m	$150m	$175m	$200m
	20%	0.71	0.73	0.74	0.76	0.77
	30%	0.74	0.76	0.79	0.81	0.83
	40%	0.77	0.80	0.83	0.86	0.89
	50%	0.80	0.84	0.88	0.91	0.95
	60%	0.83	0.88	0.92	0.97	1.01

ISLA-101 Program

ISLA-101 PoS	$0.83	$80m	$100m	$120m	$140m	$160m
	0%	0.76	0.76	0.76	0.76	0.76
	10%	0.78	0.79	0.79	0.80	0.81
	20%	0.81	0.82	0.83	0.84	0.86
	30%	0.83	0.85	0.87	0.89	0.90
	40%	0.86	0.88	0.90	0.93	0.95

Key Risks

Clinical Execution & Replication Risk

The primary valuation driver is the upcoming pivotal Non-Human Primate (NHP) study for Galidesivir; while historical data showed ~94% survival, biological variability means replication is never guaranteed. A failure to reproduce these statistically significant survival benefits in a GLP-compliant setting would invalidate the Animal Rule pathway, effectively stranding the asset given the impossibility of conducting human efficacy trials for Marburg.

Regulatory & PRV Uncertainty

While the FDA has confirmed Galidesivir's eligibility for the Animal Rule, the final award of a Priority Review Voucher (PRV) is not automatic and relies on meeting strict statutory criteria at the time of NDA approval. There is a risk that regulatory standards could shift, or that the FDA determines the data package does not fully satisfy the "predictive efficacy" or "endpoint correlation" requirements of 21 CFR 314.600, resulting in a Complete Response Letter or denial of the voucher.

Government Procurement & Commercial Risk
The commercial model relies heavily on a single dominant customer – the US Government (BARDA/SNS) – whose procurement decisions are opaque, politically driven, and subject to fluctuating budget priorities. Even with FDA approval, there is no guarantee of an immediate stockpile contract, or that the contract value will align with the high premiums seen in precedents like TPOXX or BioThrax.

Funding Risk
Island held A$6.9m in cash as of September 2025, which provides a runway for near-term milestones but leaves a narrow buffer for the NHP study (est. US$3-6m). The company's strategy assumes the receipt of non-dilutive government grants to fund this study; if these grants fail to materialize, the company will likely need to raise equity capital, potentially diluting shareholders.

Asset Concentration Risk
The company's enterprise value is disproportionately weighted towards the binary outcome of the Galidesivir program and its associated PRV monetization. Any delay, clinical failure, or regulatory setback specific to Galidesivir would likely result in a severe downward re-rating of the stock, as the secondary asset (ISLA-101) is at an earlier commercial stage with a lower probability of success

Competitive Landscape
Although the specific Marburg therapeutic market is sparse, Island faces potential competition from large pharmaceutical incumbents like Gilead (Remdesivir) or emerging vaccine developers. If a competitor with greater financial resources secures approval or a stockpile contract first – particularly one with a superior administration profile or broader label – it could significantly erode Galidesivir's market share and pricing power.

Appendix

SWOT Analysis

Strengths (Internal)	Weaknesses (Internal)
Derisked Asset History: Galidesivir has benefited from over US$70 million in prior US government funding and has an established safety profile from Phase 1 trials in over 100 healthy volunteers. **Strong Efficacy Data:** In NHP studies, Galidesivir showed ~94% survival in Marburg-infected subjects versus 0% in controls, with some dosing regimens achieving 100% survival. **Regulatory Clarity:** The FDA has explicitly confirmed the Animal Rule is the appropriate pathway for Galidesivir and that it would qualify for a Priority Review Voucher (PRV) upon approval. **Pipeline:** Beyond Galidesivir, the company has ISLA-101, a repurposed drug with a known safety profile being developed for dengue.	**Capital Constraints:** The company held A$6.9 million in cash as of 30 September 2025, while the pivotal NHP study is estimated to cost between US$3m and $6m. **Mixed Trial Results:** While ISLA-101 Phase 2a (prophylactic) data was positive, the Phase 2b (therapeutic) data showed less pronounced symptom reduction in subjects who were already viremic. **Pre-Revenue Status:** The company remains pre-revenue and relies on capital raises or grants to fund operations.
Opportunities (External)	**(Threats (External)**
Significant Cash Injection (PRV): Approval could yield a PRV, with recent precedents selling for US$100–155 million on the secondary market. Lucrative Government Contracts: US Strategic National Stockpile (SNS) contracts for similar assets have historically ranged from ~US$100 million to US$1.2 billion. **Non-Dilutive Funding:** Engagement with Todd Strategy Group targets securing government grants to fund the costly NHP study, potentially protecting shareholder equity. **Market Expansion:** Galidesivir has broad-spectrum utility against other threats like Ebola and Zika, offering potential for label expansion.	**Replication Risk:** The company's valuation depends heavily on the pivotal NHP study replicating the historical survival data; failure would severely impact the investment thesis. **Regulatory Hurdles:** Award of the PRV is not automatic and requires meeting statutory criteria at the time of approval. **Competition:** Big pharma competitors exist, such as Gilead's Remdesivir, which has shown NHP efficacy in Marburg, though it is IV-only. **Procurement Uncertainty:** Commercial success may rely on a single customer (US government), whose budget priorities can change.

Board & Management

Dr. David Foster – CEO & MD

Dr. Foster has over 25 years of experience in the pharmaceutical and biotechnology sectors, previously serving as intellectual property counsel for Medarex, which was acquired by Bristol-Myers Squibb. He co-founded the technology-focused law firm Roberts Foster LLP and the life science trade association bionorthTx, bringing deep expertise in IP strategy and commercialization.

Jason Carroll – Non-Executive Chair

Jason Carroll is a seasoned life sciences executive with over 30 years of experience, including senior leadership roles at Johnson & Johnson, Janssen Pharmaceutica, and iNova Pharmaceuticals. He brings specialist expertise in R&D, corporate strategy, and M&A, particularly within South-East Asian markets, and currently serves as the CEO of Entropy Neurodynamics (ASX: ENP).

Chris Ntoumenoloulos – NED

Chris Ntoumenopoulos has more than 20 years of experience in financial markets and is the Managing Director of Twenty 1 Corporate, an Australian corporate advisory firm. He has a strong track record of successful exits as a founding director of ResApp Health (acquired by Pfizer) and Race Oncology, and currently sits on the boards of TrivarX and Entropy Neurodynamics.

Nick McCoy – VP Clinical Product Development

Mr. McCoy is a clinical research professional with extensive experience managing global clinical teams and trials across pharmaceutical and medical device industries. Prior to joining Island, he served as Vice President of Clinical Operations at TissueTech and held roles at Palisade Bio, specializing in clinical operations and regulatory compliance.

Cameron Jones – CoSec

Mr. Jones is the Managing Director of Bio101, a financial services firm specializing in the healthcare and life science sectors. He provides accounting, tax, and secretarial services to the company and has been with Island Pharmaceuticals since its IPO.

Shareholder Register

Ranking	Shareholder Name	Shareholding	Percentage Held
1	William Gamer	41,690,073	16.37
2	Jason Carroll	31,100,000	12.21
3	Mwp Partners Limited	19,264,773	7.57
4	Daniel Tillett	14,010,000	5.50
5	KESA Partners, Inc.	11,104,034	4.36
6	David Foster	6,504,460	2.55
7	Neville Miles	5,708,237	2.24
8	Timothy Stephen Hanlon	2,853,285	1.12
9	S3 Consortium Pty Ltd	2,500,000	0.98
10	Anthony Cormack	2,140,000	0.84
11	Christopher Ntoumenopoulos	2,035,802	0.80
12	JAF Capital Pty Ltd	1,850,000	0.73
13	Donesk Family Trust	1,810,000	0.71
14	Lillucy Pty Ltd	1,500,000	0.59
15	Patricia Almeida	1,453,146	0.57
16	Helen Baker	1,403,720	0.55
17	Grayhawk Capital Pty Ltd	1,333,333	0.52
18	Ingrid Ismail	650,000	0.26
19	Yusuf Ismail	650,000	0.26
20	Lynch Thinking Investments Pty Ltd	340,000	0.13

Source: *Iress*.

Evolution Capital Ratings System

Recommendation Structure	• **Buy:** The stock is expected to generate a total return of >10% over a 12-month horizon. For stocks classified as 'Speculative', a total return of >30% is expected. • **Hold:** The stock is expected to generate a total return between -10% and +10% over a 12-month horizon. • **Sell:** The stock is expected to generate a total return of <-10% over a 12-month horizon.
Risk Qualifier	• **Speculative ('Spec'):** This qualifier is applied to stocks that bear significantly above-average risk. These can be pre-cash flow companies with nil or prospective operations, companies with only forecast cash flows, and/or those with a stressed balance sheet. Investments in these stocks may carry a high level of capital risk and the potential for material loss.
Other Ratings	• **Under Review (UR):** The rating and price target have been temporarily suppressed due to market events or other short-term reasons to allow the analyst to more fully consider their view. • **Suspended (S):** Coverage of the stock has been suspended due to market events or other reasons that make coverage impracticable. The previous rating and price target should no longer be relied upon. • **Not Covered (NC):** Evolution Capital does not cover this company and provides no investment view.

Expected total return represents the upside or downside differential between the current share price and the price target, plus the expected next 12-month dividend yield for the company. Price targets are based on a 12-month time frame.

Disclaimer & Disclosures

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