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The Path to Approval Without a Human Efficacy Trial

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Company Snapshot

Company	Island Pharmaceuticals Limited (ASX: ILA)
Lead asset	Galidesivir, a broad-spectrum antiviral given intravenously or by intramuscular injection.
Lead indication	Marburg virus disease. Second: Ebola (Bundibugyo)
Shares on issue	296,096,682
Share Price	A\$0.365
Market Capitalisation	A\$108.1m
Cash	A\$12.9m

Table 1: Share on issue, share price and market cap as of 7 October 2026, cash as of 30 June 2026.

Marburg kills around 50% of the people it infects. The Bundibugyo strain of Ebola now moving through the Democratic Republic of the Congo has killed 4,148 people this year at a fatality rate of 48% as of 7 October 2026. No vaccine or treatment is approved for Marburg, and the World Health Organization says the same for the Bundibugyo strain of Ebola. Marburg and Ebola are filoviruses, a small family of viruses that cause severe haemorrhagic fever and are among the deadliest pathogens known. The licensed products, Merck's Ervebo vaccine and the two antibody treatments from Regeneron and Ridgeback/ Emergent, are licensed for one strain only, Zaire ebolavirus.

Island Pharmaceuticals owns Galidesivir, a broad-spectrum antiviral, acquired from BioCryst Pharmaceuticals in July 2025. The US government had already spent more than US\$70m developing the molecule, and it came with completed Phase 1 human safety studies, manufacturing and regulatory data, and primate survival results in both Marburg and Ebola.

Since we last wrote about Island in July, when it secured clearance to supply Galidesivir for compassionate use in the Bundibugyo outbreak, the company has commissioned a second manufacturing campaign and begun physically making the drug, taking expected inventory to roughly 700 to 800 treatment courses by the end of this calendar year. It has also secured the natural history data the FDA asked for, which was an outstanding information requirement for its Marburg animal model, and settled the design of the two dose-finding studies that precede the pivotal trial.

Update on the Ebola program

Galidesivir has been approved for use in the Bundibugyo outbreak under MEURI, a World Health Organization framework that lets doctors give an unapproved drug to patients during an outbreak where nothing approved exists. Uganda's Ministry of Health sponsors the program, with the WHO, the ACCEPT-Africa Consortium and the Infectious Diseases Institute at Makerere University supporting it. Those institutions fund it and Island's contribution is the drug, which makes this a low-cost clinical development.

Manufacturing began physically on 1 October at PI Health Sciences. The first 5kg batch of active ingredient is due by the end of October, a second by late November.

Finding a Route into Patients

While Uganda has declared its outbreak over, the epidemic continues in the Democratic Republic of the Congo (DRC). Uganda completed the standard 42-day enhanced monitoring period on 27 August, having recorded 20 confirmed cases and two deaths in total, 15 of those imported across the border from the DRC.

As of 4 October, the DRC had recorded 8,603 confirmed cases and 4,148 deaths, implying a fatality ratio of approximately 48.2%, across seven provinces. Ituri remains the epicentre, accounting for 6,450 cases and 2,968 deaths. The outbreak was declared a public health emergency of international concern in May.

Two interventional trials are running in Ituri. PARTNERS (Platform Adaptive Randomised Trial for New and Repurposed filovirus treatments) is sponsored by the WHO and coordinated out of the University of Oxford with the DRC's Institut National de Recherche Biomedicale. It began enrolling on 2 July and had passed 300 patients by September, testing the monoclonal antibody MBP134 and Gilead's Remdesivir against supportive care, with all-cause mortality at 28 days as the primary endpoint. The second is EBO-PEP, a placebo-controlled trial of post-exposure prophylaxis in around 1,000 high-risk contacts, sponsored by INRB and France's ANRS and coordinated by ALIMA, which began enrolling in mid-July. Separately, Merck's Ervebo is being given outside its approved indication under a research protocol, with 2,007 vaccinated by 6 September.

It would be good to see Galidesivir included in one of them, and PARTNERS is the obvious target. It is an adaptive platform trial, meaning it is built to add and drop treatment arms across outbreaks rather than being fixed at launch, and it runs three domains: monoclonal antibodies, small-molecule antivirals and host-directed therapy. Galidesivir is a small-molecule antiviral and would slot into the second of those.

The Value of Treating Patients

Human data is the first prize. Galidesivir has been evaluated in two Phase 1 safety studies in healthy volunteers, one intramuscular and one intravenous, with no serious adverse events, plus a Phase 1b in 25 COVID patients where no safety signals emerged. But it has never been evaluated in humans infected with a filovirus infection. Treating Bundibugyo patients under a prospective protocol would produce clinical, safety and virological data in the actual disease.

It also strengthens the Marburg filing since Animal Rule approval rests on animal efficacy plus human safety. The preclinical basis for trying is solid: in an Ebola Zaire monkey model Galidesivir produced complete survival when treatment began two days after infection and 67% at three days, with every untreated animal dying.

Update on the Marburg program

Marburg sits in the same filovirus family as Ebola and spreads through contact with bodily fluids. WHO puts the historical fatality range at 24% to 88% depending on the outbreak and averaging around 50%. There is no approved vaccine or treatment anywhere in the world. Outbreaks are rare and have historically tended to be relatively small and short-lived.

That makes a conventional efficacy trial impossible. You cannot deliberately infect healthy volunteers with a virus that may well kill them, and natural outbreaks are usually too small, too sudden and too remote to enrol and complete a controlled study before they burn out. The FDA's Animal Rule exists for precisely this problem, allowing approval on well-controlled animal efficacy studies provided the animal model is properly characterised and human safety is established separately. Island has received confirmation from the FDA that the pathway applied to Galidesivir, together with confirmation that the drug would qualify for a Priority Review Voucher on approval.

A Priority Review Voucher is a transferable coupon the FDA awards on approval of a drug for certain neglected diseases, filovirus diseases among them. The holder can have any future drug of its choosing reviewed in six months instead of ten or can sell the coupon to another company wanting to shorten its own timeline. Recent sales have run between US\$150m and US\$205m, with Jazz Pharmaceuticals paying US\$200m in January 2026. Against ILA's market capitalisation of ~A\$108m, that is material on its own.

The Road to the Pivotal Study

The FDA set out a two-stage development pathway. Stage one is dose-finding and runs as two separate studies. USAMRIID, the US Army's infectious disease institute, will infect 20 monkeys with the Angola strain and give Galidesivir intravenously twice daily for 14 days, starting either 24 or 48 hours after infection, to establish the lowest dose that still works and measure how the drug moves through the body.

Texas Biomedical Research Institute will run a further 12 animals under the same infection model but start treatment at around three to five days when clinical signs typically appear and therefore the time a real patient would present. Between them those 32 animals are meant to fix both the dose and the treatment window.

Stage two is the pivotal efficacy study, roughly 24 animals, and that is the study an approval would rest on. The FDA has already agreed the Angola strain, the cynomolgus macaque and the viral challenge dose for all of this work. It also granted Orphan Drug Designation for Marburg post-exposure prophylaxis in June, which carries seven years of US market exclusivity on approval.

One obstacle has also recently been cleared. The FDA told Island that published information on its proposed monkey model was not detailed enough to judge whether the model was adequately characterised, and asked for the full natural history study report, meaning data on how the disease runs its course in untreated animals. That is the baseline any treatment effect gets measured against. Rather than run the study itself, Island negotiated the right to cross-reference an existing Marburg-Angola natural history dataset in its FDA submissions. Recreating that work would have meant more time in the lab, more animals and more money.

The Angola Question

Island reports 94% survival in a Marburg monkey model when treatment began up to 48 hours after infection. Across three groups of six animals, five of six survived when dosed at one hour, and six of six survived at both 24 and 48 hours, while no untreated animal survived at all. The 94% is an average pulled down by the one-hour group, and the 48-hour result that matters most was complete survival.

The catch is the strain. That work used the Musoke variant of Marburg, while the FDA's agreed model, and the pivotal study, use Angola. In dish models Galidesivir is about equally potent against the two, and the

only Angola survival data so far is a small guinea pig study in which about 75% to 100% of treated animals survived against about 25% of untreated ones. There are no Angola results in monkeys yet, which is the evidence the regulator will want to see.

Recent Milestones

- **Jul 2025.** Galidesivir program acquired from BioCryst for US\$550,000 upfront, bringing full ownership of the molecule, its Phase 1 human data and its preclinical efficacy package.
- **Nov 2025.** FDA confirmed the Animal Rule applies in Marburg and that Galidesivir would qualify for a Priority Review Voucher on approval.
- **Jan 2026.** FDA agreed the animal model, being the Angola strain, the cynomolgus macaque and the challenge dose, and set out the two-stage development pathway. US patent granted covering Galidesivir against filoviruses.
- **Feb to Mar 2026.** A\$9m placement at A\$0.35 cornerstoned by a US family office. Research agreement signed with USAMRIID and The Geneva Foundation, giving access to BSL-4 infrastructure.
- **Jun to Jul 2026.** Orphan Drug Designation granted for Marburg post-exposure prophylaxis. USAMRIID study design finalised, Texas Biomed engaged, GMP manufacturing commissioned, and approvals secured for use in Uganda under the WHO MEURI framework.
- **Aug to Oct 2026.** Second manufacturing campaign commissioned, lifting expected inventory to 700 to 800 courses by Q4 CY26. Rights secured to cross-reference the Marburg-Angola natural history dataset. GMP manufacture physically commenced on 1 October.

Next Steps

The near-term sequence is to finish the first 5kg batch by the end of October and the second by late November, start the USAMRIID dose-finding study this quarter, and begin treating patients under MEURI during the current calendar year. Texas Biomed time-to-dose study is guided to commence early 2027, the pivotal study is pencilled in for the June quarter of 2027, and NDA preparation is guided to begin in the September quarter.

The Commercial Precedent in Ebola

The model Island is aiming at already works for Ebola. Regeneron's Inmazeb is an approved Ebola therapeutic with disclosed revenue, running US\$3m in 2022, US\$70m in 2023, US\$76m in 2024 and US\$37m in 2025, underpinned by a six-year US government procurement worth roughly US\$345m. Ridgeback/Emergent's Ebanga sales are not disclosed but Emergent holds a ten-year US government contract worth up to US\$704m.

The Government Stockpile Strategy

The logic of a government stockpile starts from a market failure. A drug for a pathogen with no prevalent patient population has no commercial demand. Without an outbreak nobody buys it, and during an outbreak the affected populations are usually poor. No rational company would fund the development.

The US government's answer is to become the missing customer itself, and the Administration for Strategic Preparedness and Response (ASPR) puts the rationale plainly: without a secure source of funding, companies do not have the incentive to develop the countermeasures that are critical to national security.

Project BioShield, created in 2004, is the vehicle. It holds a Special Reserve Fund that BARDA uses to procure medical countermeasures for the Strategic National Stockpile. Two features matter for a company like Island. The first is that payment comes in two distinct forms: development contracts, which reimburse late-stage development, manufacturing scale-up and regulatory work, and procurement contracts, which buy the product itself. The second feature is that a product qualifies for purchase if it is approved by the FDA or if it could be made available under an emergency use authorisation, so full licensure is not always a precondition for a government order.

The stockpile holds US\$11.9bn of inventory and runs on about US\$1bn a year. Project BioShield's fund was US\$850m in FY2026, and the program has put 23 products into the stockpile and helped 25 through FDA approval since 2006. The FY2027 request document names late-stage development of therapeutics for Sudan virus and Marburg virus as a priority.

What contracts have actually been worth is the best guide to what Galidesivir could be worth if it works. The table below sets out the products approved under the Animal Rule that went on to government procurement, together with the two filovirus treatments approved on human outbreak data, which are the closest precedent by disease even though they took a different regulatory route.

Company, product, disease	Approved	US Government contract
SIGA, TPOXX (tecovirimat), smallpox	2018	US\$433m base in 2011, options to US\$2.8bn. Second contract 2018 up to US\$629m
Chimerix, Tembexa (brincidofovir), smallpox	2021	US\$127m base, up to US\$680m, 1.7m courses
Human Genome Sciences, raxibacumab, anthrax	2012	About US\$530m across roughly 125,000 doses
Elusys, Anthim (obiltoxaximab), anthrax	2016	Over US\$70m procured, against more than US\$350m in procurement and development contracts
Emergent, BioThrax, anthrax	2015	US\$911m over five years for about 29.4m doses
Emergent, Cyfendus, anthrax	2023	Ceiling about US\$1.6bn. Contract signed 2016, seven years before approval
Regeneron, Inmazeb, Zaire Ebola (not Animal Rule)	2020	Up to US\$344.6m over about six years
Emergent, Ridgeback, Ebanga, Zaire Ebola (not Animal Rule)	2020	Ten-year contract up to US\$704m, of which US\$121m committed

What Success Has Been Worth

SIGA Technologies is a valuable comparison, and its history shows what a stockpile contract does to a small company. Its smallpox antiviral TPOXX was approved under the Animal Rule on 13 July 2018, and BARDA signed a procurement contract worth up to US\$629m two months later. Before that sequence SIGA was a roughly US\$383m company at the end of 2017, on revenue of US\$12.3m. By the end of 2018 it was worth about US\$635m, and in the years that followed it settled into annual revenue of US\$95m to US\$140m, roughly ten times where it started. During the 2022 mpox outbreak the market capitalisation briefly reached well over US\$1bn.

Chimerix is another valuable comparable. Its smallpox antiviral Tembexa was approved under the Animal Rule in June 2021 without a human efficacy trial. BARDA signed a procurement contract with a five-year base of about US\$127m and options taking it to roughly US\$680m. Chimerix then sold the asset outright to Emergent BioSolutions for US\$238m upfront, with milestones taking the maximum consideration to about US\$374.5m.

Upcoming Catalysts

Catalyst	Expected timing	Significance
First 5kg GMP batch completed	End October 2026	Establishes the first GMP supply earmarked for the approved MEURI program.
USAMRIID 20-animal dose-finding study commences	Q4 CY26	Intended to identify the minimum effective dose and generate PK/translational data used to design the pivotal study.
USAMRIID topline results	Not currently guided	The key technical de-risking event. Needs to show efficacy in the Angola strain.
First patients treated under the WHO MEURI framework	CY26 per company guidance	First human filovirus exposure for the drug. Watch for where, given Uganda's outbreak has ended.
Texas Biomed 12-animal late-treatment study	Q1 CY27	Tests the therapeutic window at the point clinical signs appear.
Pivotal Marburg efficacy study, approximately 24 animals	Q2 CY27	Intended to support approval under the Animal Rule
Marburg New Drug Application (NDA) to the FDA	Preparation from Q3 CY27; filing date not yet guided	The formal application for approval. Approval would trigger the Priority Review Voucher and strengthen the case for a stockpile contract.

Table 2: Indicative timing only. Events may be delayed, modified or may not occur.

Global Comparisons

Island has no obvious close peers on the ASX, whose primary focus is biodefence and medical countermeasures, so the comparisons that matter are offshore. The table below sets out global listed companies in filovirus, biodefence and government stockpile antiviral development, ranked by market capitalisation. SIGA Technologies is a highly relevant comparable, being an Animal Rule approved antiviral sold into the US Strategic National Stockpile. Emergent BioSolutions and Bavarian Nordic show what the model looks like at commercial scale. The field of listed pure-play comparables is thin, because the successful ones or their assets get bought: Chimerix sold Tembexa to Emergent, Paratek was taken private by Gurnet Point and Novo Holdings in 2023.

1 USD = 1.44 AUD

1 DKK = 0.23 AUD

Company (Ticker)	Lead Asset, Indication and Delivery	Clinical Stage	Market capitalisation (AUD, m)
Bavarian Nordic (CPH: BAVA)	JYNNEOS / IMVANEX smallpox and mpox vaccine, subcutaneous	Approved, commercial, US and EU stockpile supplier	3,858.6
Emergent BioSolutions (NYSE: EBS)	ACAM2000 smallpox vaccine; CYFENDUS and BioThrax anthrax vaccines; TEMBEXA oral smallpox antiviral; raxibacumab, Anthrasil and BAT. Owns six Animal Rule approved products	Approved, commercial, US stockpile supplier	513.1
SIGA Technologies (Nasdaq: SIGA)	TPOXX (tecovirimat), smallpox, oral capsule and intravenous	FDA approved under the Animal Rule; US stockpile supplier	340.4
Tonix Pharmaceuticals (Nasdaq: TNXP)	TONMYA fibromyalgia, sublingual; TNX-801 smallpox and mpox vaccine, subcutaneous	TONMYA approved and commercial; TNX-801 preclinical, Phase 1 planned in 2027	190.0
Island Pharmaceuticals (ASX: ILA)	Galidesivir, Marburg and Ebola, intravenous and intramuscular	Approaching Pivotal animal studies	108.1
NanoViricides (NYSE American: NNVC)	NV-387 broad-spectrum nanoviricide, mpox and Ebola, oral and injectable	Phase 2	45.9

Table 3: Market cap sourced from Iress accessed 7 October 2026

Closing thoughts

The next three readouts should answer the questions that matter most. The USAMRIID dose-finding study is the first of them, and the one to watch: it has to reproduce Galidesivir's Marburg survival in the Angola strain the regulator has chosen, rather than the Musoke variant the existing data uses, and it has to establish a dose the pivotal study can be built on. The Texas Biomed study then tests whether the drug still works when treatment starts at the point a real patient would actually present. If both land, the pivotal study in mid-2027 becomes a genuinely de-risked exercise and NDA preparation follows in the September quarter.

The Ebola program is the lower-cost thread and currently the less certain one. Island holds Ugandan approvals and the majority of patients are in the DRC, so the practical question is whether Galidesivir can be written into one of the trials already running there. PARTNERS has a published route for adding an antiviral arm and Galidesivir fits the domain. If it gets in, Island generates the first human data for Galidesivir in a filovirus infection at almost no cost to itself.

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