



**ISLAND**  
PHARMACEUTICALS

# COMBATTING URGENT VIRAL DISEASE THREATS

**Dr David Foster, CEO & Managing Director**

February 2026

**ASX: ILA**

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# ISLAND PHARMACEUTICALS (ASX: ILA)

## TWO PROGRAMS TARGETING INFECTIOUS DISEASES

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Two, well advanced clinical stage programs



Major market potential via both programs



Both assets have Priority Review Voucher potential



Phase 2a/b PROTECT clinical trial in dengue complete



Positive FDA feedback on Animal Rule regulatory path



Multiple near term clinical trial, operational and regulatory catalysts

# CORPORATE OVERVIEW



Shares on issue <sup>1</sup> :	269,052,397
Price per share <sup>1</sup> :	\$0.43
Market capitalisation <sup>1</sup> :	\$115.7m
Cash at bank (31 December 2025) <sup>2</sup> :	\$6.87m
Potential additional capital from vested options where current share price exceeds exercise price:	~\$3m
Debt:	Nil

## Substantial shareholders

Dr William James Garner <sup>3</sup>	15.50%
Jason Alan Carroll <sup>3</sup>	11.92%
MWP Partners Limited <sup>4</sup>	8.25%
Dr Daniel Tillett <sup>3</sup>	7.80%

## Board of Directors

Jason Carroll, Non-Executive Chairman

Dr David Foster, CEO & Managing Director

Chris Ntoumenopoulos, Non-Executive Director

1. As at 23 January 2026

2. Does not take into consideration cash movement since reporting date

3. Per holding per Substantial interest notice lodged with ASX on 9 December 2025

4. Per holding per Substantial interest notice lodged with ASX on 3 June 2025

## Price & volume (12 months)





# COMPANY OVERVIEW

- Two clinical stage assets – Galidesivir and ISLA-101 - both with Priority Review Voucher potential based on approval
- Galidesivir:
  - Small molecule with broad antiviral activity against numerous high-priority threats
  - Robust development history with over US\$70m in funding to-date from US government
  - Opportunity to leverage FDA's Animal Rule to fast-track approval in Marburg
- ISLA-101:
  - Pre-clinical work at Monash University highlighted antiviral promise
  - 40+ Phase I, II and III human trials in cancer and respiratory diseases, and deemed safe by regulators
  - Small molecule with activity against all 4 dengue serotypes and other mosquito borne viruses
  - Successfully completed Phase 2a/b clinical trial in dengue infected subjects
- Robust balance sheet allows for execution of program development

# AN URGENT THREAT: LETHAL FILOVIRUSES & GLOBAL SECURITY



## UNTAMED KILLERS

- High Fatality Rates: Marburg up to 88%, Ebola up to 90% & Sudan up to 47%
- Limited defenses: No widely approved antivirals or vaccines for Marburg; limited countermeasures for Ebola
- BSL-4 classification: requires highest biocontainment
- Dual-use concern: history of weaponisation research and intelligence suggests these pose persistent bioterror threat

## HUMAN & ECONOMIC IMPACT

- Systemic organ failure
- Hemorrhaging
- Social/economic risk in affected regions
- Bioterror attacks with potential disastrous ramifications





# GALIDESIVIR PROGRAM OVERVIEW

- Small molecule with broad antiviral activity against numerous high-priority threats
- Robust development history with over US\$70m in funding to-date from US government
- Confirmed regulatory pathway under the FDA's Animal Rule
- Qualifies for a Priority Review Voucher on approval
- Potential to unlock government stockpile opportunities as a bioterror counter measure

1

Demonstrated activity against **20+ viruses** – many with no available treatment

2

Activity against **potential bioterror** threats

3

- Potential markets:**
- Government stockpile programs
  - Numerous antiviral programs
  - Ripe potential for partnering

# FDA RESPONSE SIGNIFICANTLY DE-RISKS REGULATORY PATHWAY



Island has the potential to become to first Australian company to gain drug approval via the FDA's Animal Rule

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FDA confirmed the Animal Rule pathway is appropriate for developing countermeasures against Marburg virus



Clear guidance provided on clinical program design – enables Island to continue to engage with the FDA and finalise plans ahead of trial commencement



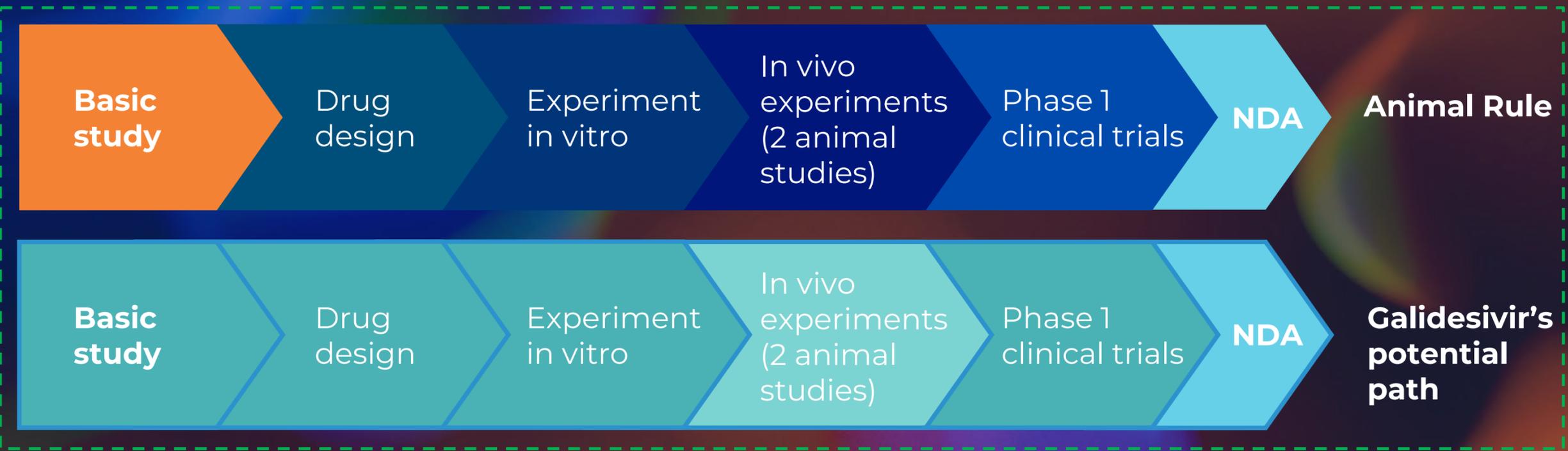
FDA advised that Galidesivir would qualify for a Tropical Disease Priority Review Voucher (PRV) on approval – Most recent PRV sold for US\$200m



Island intends to commence the next Galidesivir animal study in Marburg to advance approval in Q1 CY26 based on recently received FDA feedback



# POTENTIAL REGULATORY PATH



**Confirmed PRV opportunity with a potential value of ~US\$200m**

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Island is now focused on incorporating all FDA feedback into Galidesivir's clinical development pathway to finalise design and continue regulatory engagement

# GALIDESIVIR PROVIDES UNPRECEDENTED SPEED TO MARKET



The FDA has a number of paths for acceleration of pharmaceutical compounds to approval:

- Fast Track Designation
- Breakthrough Therapy Designation
- Accelerated Approval Pathway
- Priority Review
- **Animal Rule Pathway (Special Case)**

The Animal Rule pathway is extremely rare and limited to US National Security threats

The Animal Rule pathway is a regulatory hyper-track reserved for the most critical biothreat countermeasures

Marburg is the only Category A bioterror threat gap that remains unfilled within the Strategic National Stockpile (SNS)

All products approved-to-date under the FDA's Animal Rule have secured SNS contracts averaging ~US\$500m in lifetime value

Feature / Category (Expanded)	Oncology Asset (Fast Track)	Galidesivir (Animal Rule)
Human efficacy trials	Multiple Phase 2 and Phase 3 trials required	No human efficacy; NHP survival data accepted
Endpoints	Surrogate biomarkers; must confirm in Phase 3	Animal survival + viral clearance validated by FDA
Safety data	Starting at Phase 1 safety only	2 Phase 1 human safety studies complete
Timeline to approval	6–10 years (even accelerated)	TBD on FDA feedback
Regulatory precedent	Common in oncology approvals	Rare (<15 approvals since 2002), all national security
Commercial outcome	Competitive market entry; slow uptake to peak year sales (PYS in ~5 years)	PRV on approval and SNS procurement (PYS in year 1)
Investor upside	Targeted patient base lowers commercial cost and increases profitability	Low commercial cost structure and high price; US \$200m + long-term SNS revenues

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# BROAD SPECTRUM ACTIVITY DEMONSTRATED

Data highlights activity in vitro against multiple RNA viruses from diverse families

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

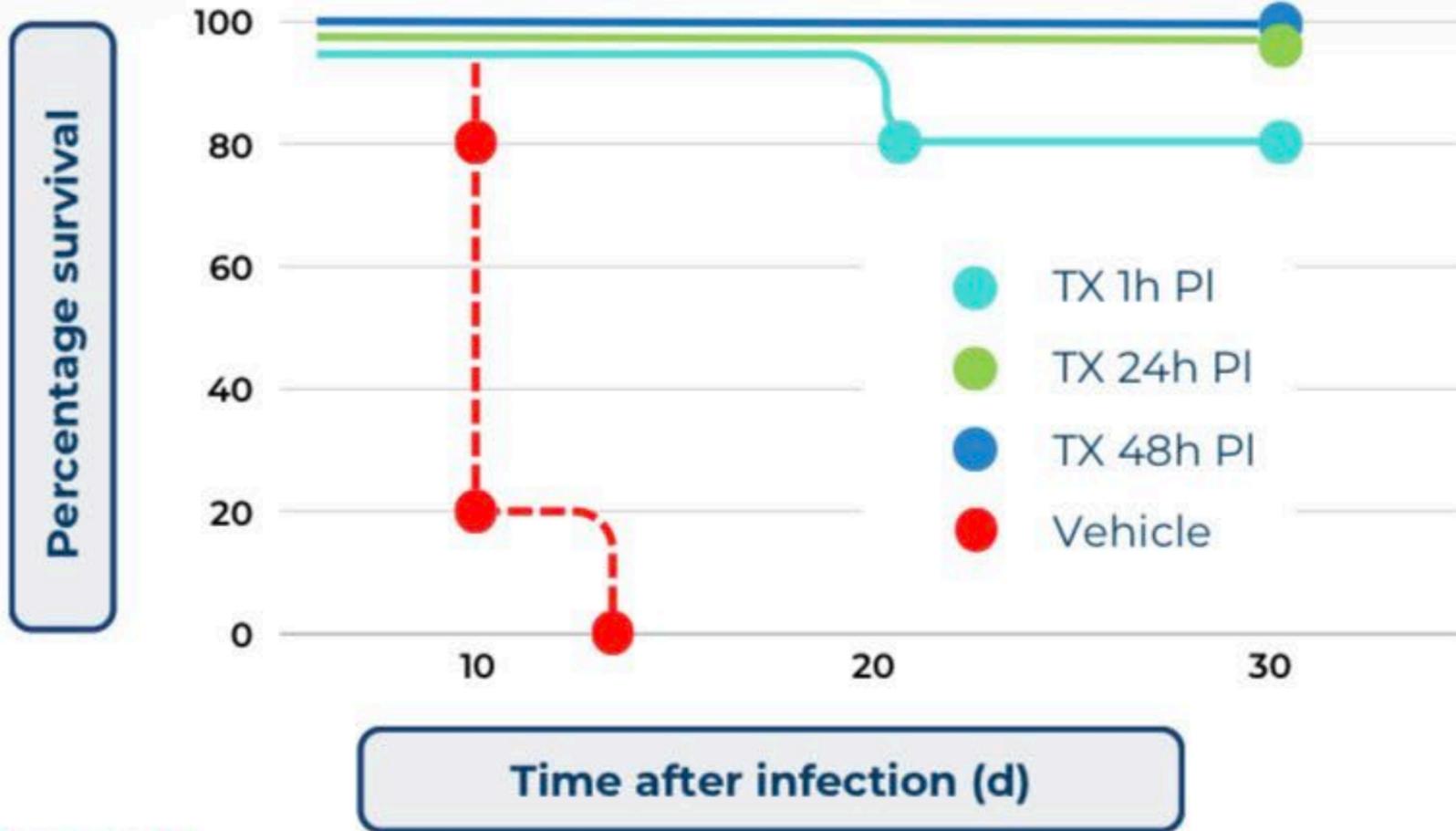
Virus Family	Virus	Strain/Variant
Paramyxo	Nipah virus	Malaysia
	HRS	A2
	Measles	Chicago
Corona	SARS-CoV	Urbani
	MERS-CoV	Jordan
Orthomyxo	Influenza	pH1N1
Picornaviridae	Rhinovirus-2	HGP
Flaviviridae	West Nile	New York
	Yellow fever	17D
	Jap. Enceph.	SA14
	Powassan Virus	LB
	Dengue 2	New Guinea C
	Zika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

# HIGH EFFICACY IN MARBURG NON-HUMAN PRIMATE STUDY



Treated non-human primates showed an overall survival rate of 94% during trial

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6/6 animals survived when dosed 48 hours post infection

6/6 animals survived when dosed 24 hours post infection

5/6 animals survived when dosed 1 hour post infection

0/6 untreated animals survived as part of the control group



# ANIMAL RULE IS A PROVEN PATH FOR BIOTERROR THREAT COUNTERMEASURES



Company	Product	Year Approved	Disease Treated	SNS Sales (AUD)	Under SNS Contract
Emergent BioSolutions	raxibacumab	2012	Inhalational Anthrax	~\$450M	Yes
Kaléo	AUVI-Q	2012	Anaphylaxis (emergency countermeasure)	~\$100M+	No (contract expired)
Emergent BioSolutions	BioThrax	2015	Anthrax (prophylactic vaccine)	~\$1.2B+ (multi-year)	Yes
Elusys Therapeutics	Anthim	2016	Inhalational Anthrax	~\$320M	Yes
SIGA Technologies	TPOXX	2018	Smallpox	~\$850M+ (ongoing)	Yes
Paratek Pharmaceuticals	Nuzyra	2018	Anthrax (post-exposure prophylaxis)	~\$120M (partial uptake)	Yes (limited scope)
Bavarian Nordic	Jynneos	2019	Smallpox / Monkeypox	~\$300M+	Yes
Chimerix	Tembexa	2021	Smallpox	~\$400M	Yes

Since 2012, the FDA's Animal Rule approval has led to 8 bioterror countermeasures joining the US Strategic National Stockpile (SNS)

In 7 out of 8 cases, these medical countermeasures continue to remain under SNS contract and have generated 'lifetime sales' of between US\$100m - US\$1.2Bn at an average of US\$467m

~US\$600m has been provided through grants to develop a Marburg countermeasure with no tangible results

Marburg is the only Category A biothreat that has no treatment presently available in the Strategic National Stockpile

FDA approval of Galidesivir in Marburg provides a significant opportunity for a Priority Review Voucher as well as a multi-year SNS contract

# GALIDESIVIR IS DESIGNED TO PROTECT THE BACKBONE OF NATIONAL RESILIENCE



ILA's stockpile strategy ensures full treatment coverage for the 10,000+ individuals critical to outbreak containment and continuity of government – from POTUS + Cabinet to Essential Infrastructure Leaders.

Tier	Estimated Headcount	Notes
President + Cabinet	~25	Includes POTUS, VP, Cabinet Secretaries
Congressional Leadership	~50	Speaker, Majority/Minority Leaders, Committee Chairs
Supreme Court	9	All Justices
National Security & Defense Heads	~100	Joint Chiefs, DHS, CIA, NSA, FEMA, etc.
Continuity-of-Government Staff	~500–1,000	Includes designated survivors, relocation site personnel
HHS/CDC/FDA Leadership	~200	Key public health and regulatory officials
State Governors + Key Staff	~1000	50 governors + emergency response leads
Tier 1 Healthcare Response Teams	~5,000–10,000	BSL-4 lab staff, frontline responders, quarantine facility personnel
Essential Infrastructure Leaders	~2,000–5,000	Power grid, water, telecom, transport continuity

## HIGH-PRIORITY RECIPIENTS FOR GUARANTEED TREATMENT COURSE

### TIER 1 -100

- President + Cabinet
- Congressional Leadership
- Supreme Court

### TIER 2 -300

- National Security & Defense Heads
- Continuity-of-Government Staff
- HHS/CDC/FDA Leadership

### TIER 3 -1,000

- State Governors + Key Staff
- Tier 1 Healthcare Response Teams

### TIER 4 -10,000

- Essential Infrastructure Leaders
- Tier 2 Response Personnel
- Allied Leadership
- Tier 3 Response Personnel
- Other Critical Workers



# MULTIPLE SHOTS ON GOAL FOR GALIDESIVIR

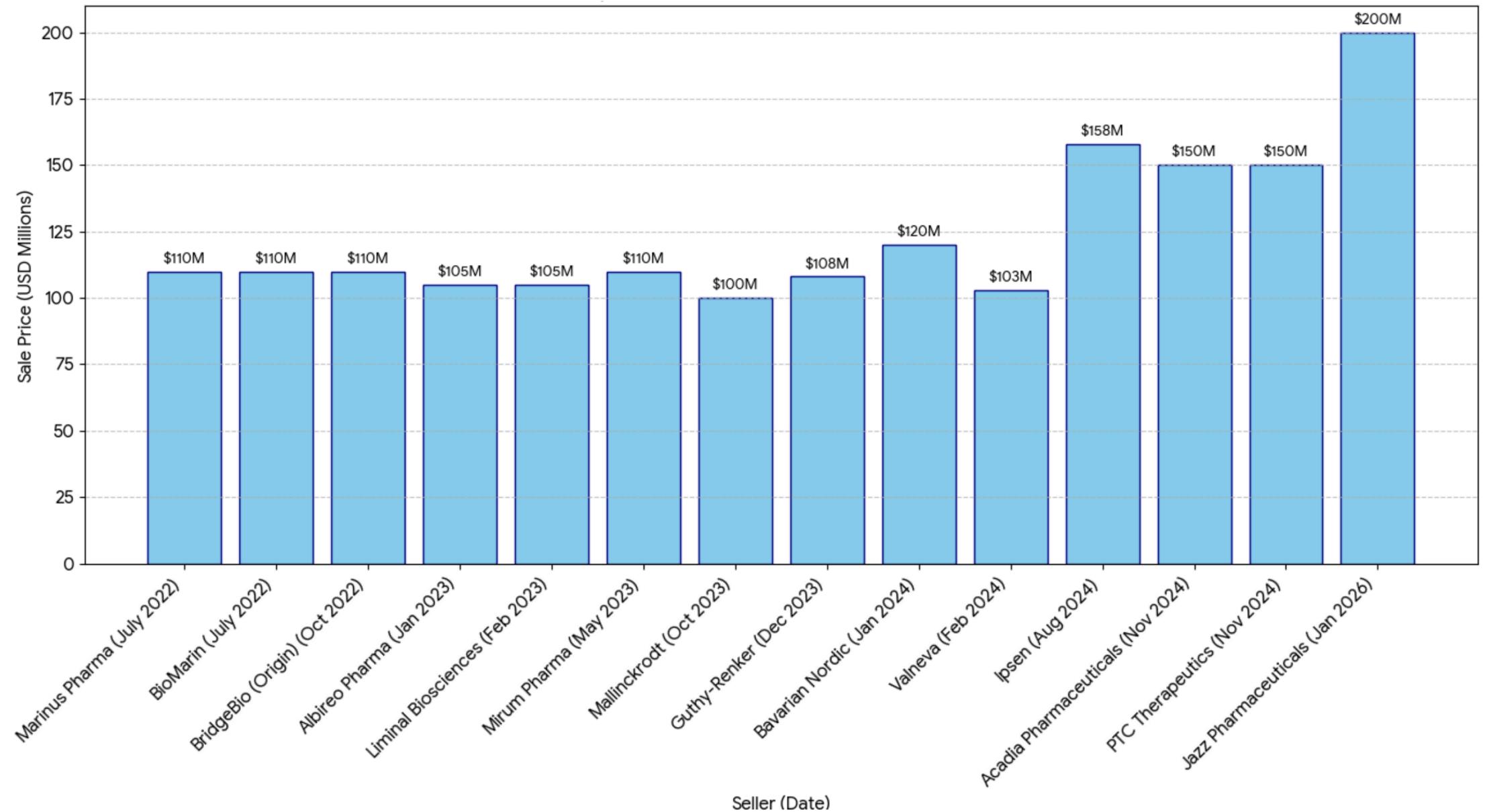
Virus	Cell culture data	Animal data	Non-human primate efficacy	PRV Eligible for first indication	Animal Rule Potential	Strategic National Stockpile Potential
Marburg	✓	✓	✓	✓	✓	✓
Ebola	✓	✓	✓	✓	✓	✓
Sudan	✓			✓	✓	✓
Zika	✓	✓	✓	✓		
Chikungunya	✓			✓		

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# PRV PRICES CONTINUE TO INCREASE



FDA Priority Review Voucher (PRV) Sale Prices (2022-2026)



- Following expiration of two forms of PRVs the price has dramatically increased over the last 18 months.
- With two programs that are currently PRV eligible, Island is in rare company with a pipeline of molecules with significant potential near-term value.



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# Galidesivir FDA Feedback & Next Steps

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# FDA FEEDBACK – KEY TAKEAWAYS

Core Animal Model Elements Confirmed

FDA requests and pathway stage-gates are clearly defined and actionable

Normal step in Animal Rule development – this is the same path taken by the last 6 Animal Rule countermeasure approvals

Expert Team and strategic partners are in place for all stages of Animal Rule pathway completion

# WHAT THE FDA HAS CONFIRMED



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Cynomolgus  
macaque =  
appropriate  
species



Angola Marburg  
Strain =  
appropriate  
challenge virus



Challenge dose  
(1,000 PFU) =  
appropriate  
challenge dose



Single animal  
species approach  
may be  
acceptable

# WHAT THE FDA HAS REQUESTED



Complete natural history dataset (Island has access to this data)



Analysis and generation of Toxicology and Pharmacokinetic (PK) data



Pivotal NHP Marburg [Angola] Study complete



Additional justification for model parameters



Refinements to NHP Study design and identification of lowest efficacious dose



File Submission under Animal Rule



# CLEAR FDA APPROVAL PATH DEFINED

**PHASE 1**  
FOUNDATION &  
ALIGNMENT  
[Q1 CY26]

**PHASE 2**  
STUDY DESIGN REFINEMENT  
& DATA INTEGRATION  
[Q2-Q3 CY26]

**PHASE 3**  
APPROVAL ENABLING  
EFFICACY PACKAGE  
[Q4 CY26]

**PHASE 4**  
REGULATORY INTEGRATION  
& SUBMISSION  
[Q1 CY27]

## **ACTION**

Provide the FDA with a complete, reviewable natural history dataset for Marburg [Angola Strain] in cynomolgus macaques

## **OUTCOME**

FDA acceptance of the natural history package

## **ACTION**

NHP Efficacy Study to generate dose-response and early efficacy signals using an FDA-aligned design in Marburg [Angola]

## **OUTCOME**

Identification of minimum efficacious dose and confirmation of study design parameters for pivotal study

## **ACTION**

Provide the FDA with PK/PD, Toxicology and Drug accumulation data – identify lowest effective dose for Marburg treatment in Animal model

## **OUTCOME**

Scientifically defensible dosing rationale for NHP studies

## **ACTION**

Pivotal NHP Efficacy Study (Animal Rule)  
Use FDA-aligned dosing, endpoints and size  
Demonstrate statistically robust survival benefit  
Collect PK data to support human bridging

## **OUTCOME**

Pivotal efficacy dataset for inclusion in Animal Rule submission

## **ACTION**

Translate NHP Efficacy exposures to human dosing. Finalise proposed human dosing regimen  
Address any final FDA questions & prepare regulatory submission (Animal Rule)

## **OUTCOME**

FDA regulatory review for approval of Galidesivir for Marburg virus infection

# OUR RESPONSE PLAN



1

Provide natural history dataset

2

Refine study and dose design to meet FDA requirements

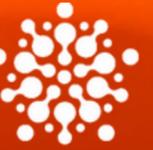
3

Complete requested Tox/PK analysis

4

Continue close engagement with the FDA for alignment on Pivotal Study

# OUR TEAM AND PARTNERS



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Deep antiviral and Animal Rule experience - team has demonstrated expertise in 14 Animal Rule approvals



Strong US Government collaborators



Access to world-class BSL-4 facilities

# WE ARE CONFIDENT OF SUCCESS



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FDA alignment on all core fundamentals to be the first Australian company to proceed through the FDA approval process via the Animal Rule pathway



Absolute clarity on the roadmap to progress – we know exactly what is required



Highly experienced team of experts, partners & collaborators



Highly disciplined execution for rapid progress through required gates



# NEAR TERM MILESTONES

A number of value catalysts pending over the coming months for Galidesivir

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Galidesivir specific milestones	Timeframe*
Commence strategic appointments to establish Galidesivir Advisory Committee	Ongoing
FDA feedback on protocol clarifying questions	Received
Commencement of Galidesivir’s development plan in non-human primates (NHP) (incl. natural history dataset)	Q1 – Q2 CY26
Galidesivir NHP minimum effective dose study and PK study (14 NHPs)	Q1 - Q2 CY26
Galidesivir NHP Time of dose post-infection study (16-20 NHP's)	Q2 - Q4 CY26
Galidesivir NHP pivotal Marburg study (~24 NHPs)	Q3 – Q4 CY26
<b>NDA preparation</b>	<b>Q1 CY27</b>
Explore partnership and international government engagement opportunities	Ongoing

\*Dates are indicative only, based on current estimates and subject to change. Number of NHPs required in pivotal study is Company’s best estimate.



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