

#### **30 October 2025**

## ASX Announcement

# **September 2025 Quarterly Activities Report**

- Acquisition of Galidesivir completed underpinning portfolio expansion
- Galidesivir is a broad acting antiviral with a robust development history and over US\$70m in R&D funding to-date from the US government
- Galidesivir works program to focus on use in Marburg by leveraging FDA's Animal Rule to fast-track approval
- Type C meeting granted with US FDA under open Investigational New Drug Application (IND) – responses expected by 12 November 2025 (US time)
- Meeting responses to provide feedback on utilising Animal Rule to fast-track Galidesivir approval for use in Marburg
- Additional feedback to provide clarity on upcoming animal study design and Priority Review Voucher eligibility
- Briefing package submitted to the FDA which includes robust data from previous clinical work undertaken using Galidesivir
- Review of historical Galidesivir data has shown high survival rates in Marburg and Ebola infected non-human primates including:
  - 94% overall survival rate in Marburg-infected primates compared to 0% survival in placebo group
  - 100% survival rate in Ebola-infected primates when administered 48 hours post-infection – compared to 0% in placebo group
- Negotiations with strategic counterparties to advance planned animal study in Marburg reaching final stages
- Cash balance of \$6.9m at 30 September 2025 underpinned by option conversion from two major shareholders totalling \$1.1m
- Options exercisable at \$0.07 per option, expiring 4 December 2025 providing up to \$1.0m in capital and exceptional financial flexibility for near term works program

**MELBOURNE Australia, 30 October 2025:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to provide the following summary of activities undertaken during the three-month period ended 30 September 2025 (**quarter**).

During the period, the Company rapidly advanced its pipeline expansion opportunities, underpinned by the acquisition of the Galidesivir antiviral program from NASDAQ-listed BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX). Upon completion of the acquisition, Island undertook a number of initiatives to accelerate Galidesivir's regulatory pathway to expedite US Food and Drug Administration (FDA) approval to position Galidesivir as a critical counter measure against high-priority viral threats for inclusion in government stockpiles.



#### **Management commentary:**

**Island's CEO and Managing Director, Dr David Foster said**: "The September quarter marked a pivotal phase for Island as we completed the acquisition of Galidesivir and rapidly advanced its path toward FDA approval. The granting of our Type C meeting request under the open IND represents a critical regulatory milestone that brings us significantly closer to potentially leveraging the FDA's Animal Rule — a mechanism designed to fast-track access to vital medical countermeasures where human trials are unethical or not feasible.

Our submission to the FDA included an exceptionally strong dataset, with historical studies showing survival rates of up to 94% in Marburg infected non-human primates, underscoring the strength and potential of Galidesivir as a broad-spectrum antiviral. We expect formal feedback from the FDA in November, which will provide important clarity on the design for our upcoming animal study and Priority Review Voucher eligibility.

It was also pleasing to see the continued support of our major shareholders during the quarter, with more than \$1.1m raised through option exercises. This additional capital provides Island with exceptional financial flexibility to execute on our near-term works program, including the upcoming animal study and ongoing regulatory engagement.

We enter the December quarter with clear momentum, a strengthened balance sheet, and a sharpened focus on establishing Galidesivir as a leading antiviral candidate capable of addressing global health and biodefence priorities."

#### **Operational overview:**

# **Acquisition of Galidesivir:**

Island executed an asset purchase agreement to fast track the strategic acquisition of the Galidesivir antiviral program from NASDAQ-listed BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX). The agreement followed a Letter of Intent with an option for rights to the molecule in 2024 (refer ASX announcement: 11 September 2024).

Galidesivir is a clinical-stage antiviral molecule with a broad spectrum of activity in over 20 RNA viruses, including high-priority threats such as Marburg, Ebola, MERS, Zika and Yellow fever – viruses with significant unmet medical needs and that may contribute to national security threats.

The program has a robust development history, underpinned by upwards of US\$70m in funding support from the US government in recent years. This capital was deployed towards clinical development, targeting Marburg and subsequently, Yellow Fever and Ebola virus disease, including drug development, manufacturing, preclinical and clinical trial support.

At the commencement of its development pathway, the program was designed to target significant threats. It was then expanded to include other emerging infectious diseases, including MERS and Zika for emergency disease outbreaks, later evolving further to pursue other RNA viruses.

The acquisition included robust clinical trial data, containing completed Phase 1 studies in healthy volunteers including single ascending dose and multiple ascending dose intramuscular administration studies, as well as intravenous single ascending dose studies.



The data package also includes a successful non-human primate study in Marburg, which provides a strong foundation for upcoming clinical trial requirements associated with the US FDA's Animal Rule.

The Company is currently focused on utilising the FDA's Animal Rule to advance Galidesivir to a New Drug Application (NDA). The rule allows for approval of drugs in indications based on animal efficacy data, when human trials are unethical or not feasible, provided safety is shown in humans and the disease is well modelled in animals.

It is anticipated that NDA approval may provide Island with access to a Priority Review Voucher (PRV), which is a program implemented by the FDA to incentivise drug development for neglected diseases. Most recently, PRV's have been valued in excess of US\$150m. Post approval, the Company target a number of opportunities to capitalise on the asset as a bioterrorism countermeasure.

#### FDA initiatives to accelerate Galidesivir approval

During the period, the Company made significant progress in Galidesivir's regulatory pathway through direct engagement with the FDA.

Island lodged a Type C meeting request with the FDA under its existing Investigational New Drug (IND) application. The meeting request sought guidance on the design of Island's upcoming non-human primate study in Marburg, the potential application of the Animal Rule for Galidesivir's approval, and eligibility for a PRV, which could accelerate market access and enhance the program's commercial value.

Shortly after the request was lodged, the FDA formally granted the Type C meeting request, confirming that written feedback would be provided to Island by 12 November 2025 (US time) – Pleasingly, this guidance was confirmed by the FDA subsequent to the end of the period. This correspondence represents a key milestone in advancing Galidesivir's regulatory trajectory and is expected to provide important clarity around study design requirements and next steps towards potential approval.

To support the FDA's review process, Island submitted detailed briefing materials summarising Galidesivir's historical clinical data, non-human primate efficacy findings, pharmacokinetic and safety profile, and justification for Animal Rule applicability. Concurrently, the Company continues to progress negotiations with specialist research organisations in preparation for the planned animal efficacy study.

#### Historical Galidesivir data shows high level survival rates in Marburg and Ebola:

Island provided key findings from an ongoing review of the Galidesivir data package, which formed part of the Company's ongoing engagement with the FDA. These findings highlighted high level survival rates in previous clinical studies undertaken in non-human primates in Marburg and Ebola respectively. A summary of these results is as follows:

94% survival rate in Marburg from non-human primate study undertaken by BioCryst:

Galidesivir was administered one hour, or one or two days post Marburg virus infection. This led to an overall survival rate of 94%, including a 100% survival rate when treatment began on day one or day two post infection. This is compared to the placebo group, which succumbed to infection within ~10 days, confirming lethality from infection without intervention.



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

Exceptional survival rates in Ebola from BioCryst non-human primate studies:

BioCryst historically undertook non-human primate studies to test Galidesivir's utility in Ebola. During the initial study, Galidesivir was administered on day two or three post infection, followed by a maintenance dose for a further 9 days. The outcome of this study delivered a 100% survival rate when dosing began on day two and a 67% survival rate when it commenced on day three.

These results highlight that Galidesivir protected non-human primates against an otherwise lethal Ebola infection, depending on the timing of administration. The Company plans to pursue additional studies in Ebola at a later date.

Summary of historical Ebola non-human primate studies:			
Group	Time post infection	Survival (no.)	Survival (%)
Placebo (untreated)	-	0/6	0%
Galidesivir treated	48 hours	6/6	100%
Galidesivii treated	72 hours	4/6	67%

These results are underpinned by robust data in more than 100 subjects including two Phase I studies in humans.

#### **ISLA-101** progress:

Island continues to collect data from its Phase 2a PROTECT study which demonstrated reduced viremia in both prophylactic and treatment arms, as well as improved symptoms in the prophylactic cohort while delivering surprising changes in biomarkers associated with infection in the treatment arm.

The Company is consulting with a number of key opinion leaders and its Scientific Advisory Board (SAB) members to advance the design of a Phase 2b clinical trial in dengue infected patients.

In addition, the Company has undertaken reformulation efforts to design proprietary oral and intravenous formulations of ISLA-101 that may have applicability in both prophylactic and treatment settings.

### **Corporate:**

#### Appointment of Jason Carroll as Non-Executive Chairman:

During the quarter, Mr Jason Carroll commenced as Non-Executive Chairman. Mr Carroll is a highly regarded healthcare executive and brings over 30 years of experience in the field of life sciences.

During his career, he has held senior leadership roles at several multinational pharmaceutical companies including Johnson & Johnson, Janssen Pharmaceutica and iNova Pharmaceuticals.



Mr Carroll brings specialist expertise in both R&D and corporate strategy. His extensive experience in clinical product development includes oversight of successful market access and reimbursement programs for new drug treatments, alongside the delivery of regional M&A and business development strategies with a focus on South-East Asian markets.

Mr Carroll is a substantial shareholder in Island. The Company expects to considerably benefit from his strategic oversight and expertise.

Alongside Mr Carroll's appointment, Mr Phil Lynch stood down to focus on other interests. Island sincerely thanks Mr Lynch for his contribution and wishes him well in his future endeavours.

#### Options exercises strengthen financial position and highlight shareholder support:

During the quarter, Island secured additional funding through the exercise of options by two major shareholders.

Island co-founder and major shareholder, Dr William Garner exercised options to raise approximately \$780,000, reinforcing his long-term commitment to the Company. This was followed by MWP Partners Limited, a Hong Kong-based investment firm and substantial shareholder, exercising 5 million options at \$0.07, contributing a further \$350,000 in new funding.

Combined, these exercises delivered over \$1.1m in additional capital, strengthening Island's financial position and providing increased flexibility to advance near term clinical development and regulatory milestones.

The participation of both a cornerstone shareholder and a major institutional investor represents a strong vote of confidence in Island's leadership, strategic direction, and progress toward upcoming regulatory milestones.

#### Promotional and shareholder engagement activities:

Island undertook multiple shareholder engagement and promotional initiatives during the period, providing the management with the opportunity to engage directly with Australian and international investors, as well as potential strategic partners.

This included a series of investor meetings in Australia undertaken by Dr David Foster and Mr Jason Carroll and encompassed presentations to several institutions and professional investors, as well as attendance at the annual BioShares conference in Hobart. Further, management also undertook a number of investor webinars which related to major developments including the acquisition of Galidesivir, as well as finding from ongoing review of the historical data package.

Further, the Company was also represented at the 2025 Dengue Endgame Summit on Wednesday, 13 August 2025 in Syracuse New York and hosted by SUNY Upstate's Global Health Institute by Dr Bert Slade, Island's Chief Medical Officer.

#### Financial summary:

Island's cash position at 30 September 2025 was \$6.9m (as at 30 June 2025: \$7.2m). Net cash used in operating activities totalled \$820,000, which included costs related to R&D, administration and corporate costs.



In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C were \$221,000, which includes salary and FY25 STI bonus for the CEO/Managing Director and Director fees (including superannuation) for the Executive Chair, Non-Executive Chair and Non-Executive directors and their consulting fees as announced to the ASX.

#### - Ends -

## Approved for release to the ASX by:

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#### **About Island Pharmaceuticals**

Island (ASX: ILA) is a drug repurposing company, focused on areas of unmet need for antiviral therapeutics to address infectious diseases. Our lead asset is ISLA-101, a drug with a well- established safety profile, being repurposed for the prevention and treatment of dengue2 fever and other mosquito (or vector) borne diseases.

If ISLA-101 achieves FDA approval, and certain other criteria are met, Island may be eligible to obtain a "Priority Review Voucher" at the time of FDA approval. This means that as well as getting approval to manufacture and sell ISLA-101, the Priority Review Voucher (PRV) could permit Island to expedite the FDA approval process for a new drug or sell the PRV in a secondary market.

Island encourages all current investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, whose contact info is housed on the Shareholder Services page of the Company's website.

Visit www.islandpharmaceuticals.com for more on Island.

# **Appendix 4C**

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

# Name of entity

ISLAND PHARMACEUTICALS LIMITED

Quarter ended ("current quarter")

ABN

48 641 183 842 30 September 2025

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for	-	-
	(a) research and development	(364)	(364)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(135)	(135)
	(f) administration and corporate costs	(378)	(378)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	57	57
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		-
1.9	Net cash from / (used in) operating activities	(820)	(820)

2.	Cash flows from investing activities	
2.1	Payments to acquire:	
	(a) entities	-
	(b) businesses	-
	(c) property, plant and equipment	-
	(d) investments	-
	(e) intellectual property	(845)

ASX Listing Rules Appendix 4C (17/07/20)

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(845)	(845)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,315	1,315
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	1,315	1,315
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,252	7,252
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(820)	(820)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(845)	(845)

ASX Listing Rules Appendix 4C (17/07/20)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,315	1,315
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
4.6	Cash and cash equivalents at end of period	6,900	6,900

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	331	286
5.2	Call deposits	6,569	6,966
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	6,900	7,252

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	221
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

The amount at 6.1 includes salary and FY25 STI bonus for the CEO/Managing Director and Director fees (including superannuation) for the Executive Chair, Non-Executive Chair and Non-Executive directors and their consulting fees, where applicable.

7.	Financing facilities
	Note: the term "facility' includes all forms of financing
	arrangements available to the entity.
	Add notes as necessary for an understanding of the

Add notes as necessary for an understanding of the sources of finance available to the entity.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-
-	-
-	-

7.5 Unused financing facilities available at quarter end

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(820)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	6,900
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	6,900
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	8.4

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

# **Compliance statement**

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

	30 October 2025
Date:	
	The Board
Authorised by:	(Name of body or officer authorising release – see note 4)

#### Notes

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- 2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.