

# 30 January 2025

# ASX Announcement

# December 2024 Quarterly Activity Report and Appendix 4C

- ISLA-101 shows safety and anti-dengue activity in the Phase 2a prophylactic arm of the Phase 2a/b PROTECT clinical trial in dengue fever
- Phase 2b therapeutic arm commenced post quarter, following submission of Phase 2a data to US FDA
- Mr. Phillip Lynch appointed Executive Chairman, bringing extensive consumer healthcare and biotech experience and expertise to the Board
- A\$3.5 million secured via a two-tranche placement to sophisticated and specialist biotech investors, funding the Company to achieve its ISLA-101 Phase 2b trial read out and explore pipeline expansion opportunities
- Island closed the quarter with a cash position of \$3.99million

**MELBOURNE Australia, 30 January 2025:** Australian antiviral drug development company, Island Pharmaceuticals Ltd (**ASX: ILA**; **Island** or **the Company**) is pleased to release its Appendix 4C and quarterly business activities update for the three-month period ended 31 December 2024 (Q2 FY25).

CEO of Island Pharmaceuticals, Dr David Foster said, "Q2 FY25 has been a pivotal quarter for Island Pharmaceuticals, marked by significant progress in our ISLA-101 Phase 2a/b PROTECT clinical trial in dengue fever. We're very pleased to have completed the dosing of subjects in the Phase 2a prophylactic arm and to have recorded positive safety and anti-dengue activity. These achievements demonstrate the potential of ISLA-101 to address the major unmet need for effective treatments against dengue fever.

With our recent A\$3.5 million placement, we are well-funded to drive our clinical programs forward and explore new opportunities for growth. We are pleased to have strengthened our team through the December quarter with the appointment of Mr. Phillip Lynch as Executive Chairman and look forward to his guidance and expertise as we navigate the next phase of our development. As we move into the new year, we're strongly focused on delivering our trial milestones and moving our pipeline expansion program along."



# **Key Announcements**

On 3 October 2024, Island announced that it had dosed subjects in its Phase 2a/b PROTECT clinical trial. On the same day, Island also announced it had received firm commitments for a placement of A\$3.5m at A\$0.07 per share, plus an attaching option for each share issued. This investment ensures Island is well-funded, enabling the achievement of critical near-term inflection points and pipeline build.

On 11 November 2024, Island announced that Dr Paul MacLeman and Dr Anna Lavelle had advised of their intentions to retire from the Island Board at the Company's 2024 Annual General Meeting.

On 15 November 2024, Island announced that Mr Phillip Lynch had been appointed Executive Chairman, effective following the 2024 Annual General Meeting.

On 18 November 2024, Island announced progress on its ISLA-101 Phase 2a/b clinical trial in dengue fever. All key data samples had been collected following dosing of all subjects in the Phase 2a (prophylactic) trial as part of Island's ISLA-101 Phase 2a/b PROTECT clinical trial in dengue fever.

On 27 November 2024, Island announced that the Safety Review Committee (SRC) concluded that ISLA-101 had shown safety and antidengue activity in the Phase 2a cohort of the PROTECT Phase 2a/b trial. No safety concerns were seen by the SRC that necessitated implementing any defined individual or study changes. SRC recommended that Island proceed with the Phase 2b cohort (the therapeutic cohort) of the Phase 2a/b PROTECT clinical trial.

On 2 December 2024, Island advised that, owing to work commitments, Dr Leigh Farrell had resigned from his position as a member of the Company's Scientific Advisory Board (SAB).

On 11 December 2024, Island announced that a key patent relating to the Company's lead drug candidate, ISLA-101, had been granted by the United States Patent and Trademark Office (USPTO).

On 20 December 2024, Island released the Notice of Meeting for the Extraordinary General Meeting (spill meeting).

# **Clinical Trial Update**

During the quarter, Island dosed all subjects in the Phase 2a prophylactic arm of its ISLA-101 Phase 2a/b PROTECT clinical trial in dengue fever, with all key data samples collected.



The Company announced that the SRC observed positive safety and antidengue activity in the Phase 2a cohort, demonstrating the potential of ISLA-101 to address the significant unmet need for effective treatments against dengue fever.

Importantly, blood levels of ISLA-101 were seen as expected in subjects that received the drug, confirming that it achieved its target concentration. This excellent outcome demonstrated that the dose-finding work and in silico modelling conducted during and after the ISLA-101 Single Ascending Dose study (ASX: 3 June 2024) led to an appropriate dosing regimen.

The SRC, comprised of leading dengue experts reviewed the data and recommended that Island proceed with the Phase 2b therapeutic arm.

Subsequent to that time, Island submitted the SRC's recommendation to the US Food and Drug Administration (FDA) for review. Following the mandated 30 day FDA review period, Island is now advancing the Phase 2b therapeutic arm

The Phase 2 study is divided in to two cohorts, a Phase 2a (prophylactic) and Phase 2b (therapeutic) cohort. The Phase 2a study examined the prophylactic (preventative) arm of ISLA-101 in dengue fever, involving four subjects randomised 3:1 (active: placebo). Phase 2b is the therapeutic (treatment) arm of the trial and will involve 10 subjects, randomised 8:2 (active: placebo). The first four subjects were enrolled in January (ASX: 8 January 2025), with the second group of six subjects, enrolled 21 January 2025 (US time).

The difference between the Phase 2a and Phase 2b cohorts is significant in respect of study aim. In the Phase 2a cohort, the subjects were pre-treated with ISLA-101 before exposure to the challenge virus. The question being explored in Phase 2a was: "can ISLA-101 prevent or reduce infection when administered prior to exposure to the virus?" By contrast, in the Phase 2b cohort, the question is: "can ISLA-101 reduce symptoms in an individual who is already infected with the dengue virus?" Between the two studies, Island aims to understand whether or not ISLA-101 can be an effective prophylactic (preventative) and/or therapeutic (treatment) against a dengue infection.

High level results from the Phase 2b study are anticipated to be available around April 2025 and full results from both cohorts' unblinded data is expected in Q4 FY25. The Phase 2b trial remains fully funded and the recent \$3.5 million placement allows ILA to pursue its additional pipeline targets.

# **Corporate Activities**

On 4 October 2024, Dr David Foster presented at the 2024 iC<sup>3</sup> Life Science Summit and represented Island Pharmaceuticals as a Rising Star award winner.



On 8 October 2024, Island held a special investor webinar, where CEO, Dr David Foster provided an update on the Phase 2a/b PROTECT clinical trial and the recent Placement. A recording of the webinar can be accessed <u>here</u>.

On 11 October 2024, Island was featured in a Bioshares report titled 'Island *Pharmaceuticals Shares Surge on Trial Start and Capital Raise'*, which highlighted that ISLA-101 had gone through rigorous preclinical studies showing a demonstrated safety profile and promising efficacy. The report is available <u>here</u>.

On 13 November 2024, Dr David Foster participated in a Stock Soiree investor event hosted by MarketOpen in Perth, where he showcased Island to potential investors.

On 15 October 2024, Pitt Street Research released an initiation research report on Island. The research report is available <u>here</u>.

On 15 November 2024, Island held a special in-person information session in Melbourne where Dr David Foster provided updates on the ISLA-101 Phase 2a/b PROTECT clinical trial, discussed the galidesivir due diligence program and covered other recent developments.

On 19 November 2024, the Island 2024 Annual General Meeting (AGM) was held in Sydney and was accessible virtually. Results from the AGM can be viewed <u>here</u>.

On 20 November 2024, Dr David Foster presented at Monsoon's Twilight Investor Briefing, providing updates on the ISLA-101 Phase 2a/b clinical trial in dengue fever, and progress on Island's pipeline expansion program.

On 27 November 2024, Island held an online briefing session for investors where Dr David Foster discussed the positive Safety Review Committee findings from the Phase 2a component of Island's Phase 2a/b clinical trial in dengue fever.

On 30 November 2024, Island was featured in a detailed analysis in an issue of Bioshares titled 'Island Pharmaceuticals Achieves Endpoints in Phase 2a Study in Dengue Fever'. The report is available <u>here</u>.

On 5 December 2024, Pitt Street Research released a research report on Island following the ISLA-101 Phase 2a dengue fever clinical trial results. The research report is available <u>here</u>.

Post-quarter Al Hansen departed the Board following the EGM on 28 January 2025. Island thanks Mr. Hansen for his time with the company.



# **Partnering Activities**

Island continues to explore pipeline expansion opportunities and in particular continues to perform due diligence on the broad acting antiviral molecule, galidesivir. A team of expert consultants are currently reviewing all aspects of the program, including intellectual property, manufacturing, human clinical and animal preclinical data and regulatory strategies. In further support of these efforts in respect to the galidesivir opportunity, Island has engaged an organisation specialising in securing government funding and providing ongoing project management support to government funded programs.

## **Financial Summary**

Island's cash position was A\$3.99 million as at 31 December 2024 (A\$0.72 million as at 30 September 2024). During the December 2024 quarter total cash operating outflows were approximately A\$1.0million partially offset by the receipt of 2024FY R&D refund of \$865k, resulting in net cash operating outflows of \$135k as the Company progresses its ISLA-101 Phase 2a/b PROTECT clinical trial in dengue fever.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C was A\$201k and included Director fees, salary and superannuation for the CEO/Managing Director, Executive Chair and Non-Executive Directors.

During the December 2024 quarter, the Company completed a two-tranche placement to existing and new investors to raise approximately A\$3.5 million at 7 cents (A\$0.07) per share with an attaching unlisted option for each share issued (Placement). The attaching unlisted options have an exercise price of 7 cents (A\$0.07). 50% of the options will expire on 4 December 2025 (12 months from issue) and the remaining 50% will expire on 4 December 2026 (24 months from issue). The Placement was approved by shareholders at the Annual General Meeting on 19 November 2024 and was managed by Island directly, with no broking fees paid to external parties.

- Ends –

To subscribe to Island's monthly newsletter, <u>IslandWatch</u>, and other forms of email communications, please visit <u>this page</u> of our website.

## Approved for release to the ASX by:

The Board of Directors. Island Pharmaceuticals Limited



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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 theCompany's share registry, Automic Registry Services, whose contact info is housed on theShareholder Services page of the Company's website.

Visit <u>www.islandpharmaceuticals.com</u> for more on Island.

# Appendix 4C

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

### Name of entity

### ISLAND PHARMACEUTICALS LIMITED

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Quarter ended ("current quarter")

31 December 2024

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for	-	-
	(a) research and development	(348)	(831)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(104)	(208)
	(f) administration and corporate costs	(548)	(902)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	865	865
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(135)	(1,076)

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	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 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	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	3,506	3,506
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	335	342
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(449)	(449)
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	3,392	3,399
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	724	1,660
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(135)	(1,076)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000	
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,392	3,399	
4.5	Effect of movement in exchange rates on cash held	11	9	
4.6	Cash and cash equivalents at end of period	3,992	3,992	

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	3,992	724
5.2	Call deposits	-	-
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)	3,992	724

6.	Payments to related parties of the entity and their
	associates

Aggregate amount of payments to related parties and their

6.1

Current quarter \$A'000					
	201				
	-				

6.2 Aggregate amount of payments to related parties and their associates included in item 2

associates included in item 1

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 Director fees, salary and superannuation for the CEO/Managing Director, Executive Chair and Non-Executive directors.

### 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 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

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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.

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8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	(135)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	3,992
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	3,992
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	29.6

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**

- 1 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 January 2025

Date:

The Board

#### 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.