

**28 April 2022**

## **ASX Announcement March 2022 Quarterly Activity Report and Appendix 4C**

- Final clinical drug product for Island’s ISLA-101 Phase 2a dengue fever clinical trial planned for May/June 2022
- Pipeline expansion underway, targeting other viruses with significant unmet need and limited competition
- Island closed the quarter with a strong cash position of A\$5.309m

MELBOURNE Australia, 28 April 2022: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; “Island”; “the Company”) pleased to release its Appendix 4C and quarterly business activities review for the three month period ended 31 March 2022 (Q3 FY22).

CEO of Island Pharmaceuticals, Dr David Foster said, *“The Island team spent the March quarter operationally focused on preparations to produce final clinical drug product for the ISLA-101 Phase 2 trial and to position us for filing our Investigational New Drug application with the USFDA.*

*We are gaining profile and are delighted to have recently been one of a small number of companies invited to bring our expertise to an invitation only summit focusing on “Flaviviruses: Epidemiology, Pathogenesis, Immunology, and Medical Countermeasures Development alongside government, military and NGO participants.*

*Finally, we spent some time investigating potential disease areas which might make sense for pipeline expansion and look forward to update the market on those in coming months.”*

### **Corporate summary**

Island Pharmaceuticals listed on the ASX following an oversubscribed A\$7.5m Initial Public Offer (IPO) on 13 April 2021. Funds raised under the IPO are enabling Island to conduct a Phase 2 study of its lead drug candidate ISLA-101 and provide working capital for research and development. ISLA-101 is a drug with a very well-known safety profile, being repurposed as a potential preventative for dengue fever.

Island remains well positioned to execute a rapid path to the clinic for ISLA-101. Since listing, the Company has been focused on executing on the structured delivery of its ISLA-101 clinical trial. To this end, the Company has engaged an additional CMC/Regulatory consultant, Kevin Swiss. Dr. Swiss has more than 30 years of CMC and Regulatory experience, including time at the United States Food and Drug Administration (US FDA) and numerous pharmaceutical companies.

Island’s CEO, Dr David Foster is honoured to have received in invitation to and will be attending a summit focusing on *“Flaviviruses: Epidemiology, Pathogenesis, Immunology, and Countermeasure Development.”* This invitation only event is hosted by the Trudeau Institute and the State University of New York Upstate Medical University, Institute for Global Health and Translational Sciences, and will be attended by thought leaders with expertise in Flaviviruses and pandemic preparedness from academia, government and industry.



Island also received an invitation to present at the upcoming BIO conference to be held in June, 2022 in San Diego, CA.

Immediately post quarter, Island was invited to speak at the PAC Partners inaugural Healthcare conference. Through this event and in a subsequent roadshow Dr Foster held a series of meetings with existing and potential investors.

### **ISLA-101 trial preparation**

Island is able to leverage the significant pre-existing body of clinical data for ISLA-101 as well as data from previously filed INDs in the US to expedite its path into the clinic for its PEACH trial. The PEACH trial is a Phase 2a, randomized, double blind, placebo-controlled study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model.

A dengue human infection model (DHIM) clinical trial sponsored by U.S. Army Medical Research and Development Command was recently completed. Island has access to the control data from this clinical trial under the Cooperative Research and Development Agreement (CRADA) it has in place with the U.S. Army Medical Materiel Development Activity. The control data will be used in Island's Phase 2 PEACH study, as agreed previously with the US FDA. Access to this data greatly reduces time and cost for Island in the conduct of the PEACH study.

Through the quarter, Island continued to progress the Chemistry, Manufacturing and Controls tasks required to file an Investigational New Drug (IND) application with the US Food and Drug Administration necessary for the commencement of its PEACH clinical trial.

Despite delays incurred in the manufacturing timeline, Island remains focused on finalising manufacturing in the current quarter (Q4 FY22) and filing the IND application and initiating the PEACH study as soon as possible after the IND is approved by the FDA.

### **Pipeline development and intellectual property**

A data driven analysis of around 150 viruses was completed by a third party expert virologist.

Around 150 viruses were reviewed and prioritised by:

- Medical relevance for the Americas, Europe and Oceania
- Significant unmet need
- Limited competition
- Insight into virus mechanism/life cycle

Exemplary viruses that met these criteria included:

- Zika virus
- Human respiratory syncytial virus
- Human cytomegalovirus, and
- Epstein-Barr virus

Island's Scientific Advisory Board will meet to prioritise viruses identified in this analysis to nominate specific targets in the two previously announced research collaborations with Monash and Griffith Universities.

## Financial Summary

Island's cash position was A\$5.31million as at 31 March 2022 (A\$5.83million as at 31 December 2021). During the March 2022 quarter total cash operating outflows were approximately A\$442,000 (A\$414,000 in the prior quarter), largely due to R&D costs in relation to the challenge study and the preparation for the Phase II clinical study, including CRO expenses, manufacturing expenses and fees paid to SUNY Upstate.

A summary of the operating cashflows for twelve months ending 31 March 2022 compared with the proposed use of funds in Year 1 (twelve months) of Island's Prospectus dated 26 February 2021 is outlined below:

	Y1 First 12 Months (A\$)	Y1 Per Prospectus (A\$)
<b>Clinical, regulatory and implementation</b>	395,000	2,027,000
<b>IP research and development</b>	33,000	139,000
<b>Formulation development</b>	-	-
<b>Working capital and administration costs</b>	1,441,000	1,195,000
<b>Expenses of the offer costs</b>	450,000	450,000
	<b>2,319,000</b>	<b>3,811,000</b>

During the twelve-month period ending 31 March 2022, overall spend was lower than estimated in the use of funds as set out in the Prospectus as a result of the change in API supply, delays in manufacturing and delayed receipt of invoices from third parties. The Company expects R&D expenditure to significantly increase in the coming quarters as the Company prepares for the ISLA-101 Phase II clinical study. The Company believes the working capital outflows are consistent with the requirements for an ASX listed biotech company of its size.

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\$107,000 and included Director fees, salary and superannuation for the CEO/Managing Director, Executive Chair and Non-Executive directors.

### Approved for release to the ASX by:

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 Executive Chairman  
 Island  
 Pharmaceuticals Ltd  
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## About Island Pharmaceuticals

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Island (ASX: ILA) is a mid-clinical-stage drug repurposing company, focused on the topical area of antiviral therapeutics for infectious diseases. Our lead asset is ISLA-101, a drug with a well-established safety profile, being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases. The Company is close to commencing a Phase 2a clinical trial in dengue-infected subjects.

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](http://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

**ABN**

48 641 183 842

**Quarter ended ("current quarter")**

31 March 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(204)	(392)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(64)	(191)
(f) administration and corporate costs	(174)	(578)
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	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(442)</b>	<b>(1,161)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>
<b>3. Cash flows from financing activities</b>		
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	-	-
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)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>-</b>	<b>-</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	5,829	6,461
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(442)	(1,161)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(78)	9
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>5,309</b>	<b>5,309</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	5,309	6,262
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>5,309</b>	<b>6,262</b>

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

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

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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.

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

**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.*

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-

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.

N/A

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(442)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	5,309
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	5,309
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>12.0</b>

*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.

Date: 28 April 2022

Authorised by: The Board of Island Pharmaceuticals Limited  
(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.