**27 April 2023**

# ASX Announcement
# March 2023 Quarterly Activity Report and Appendix 4C

- FDA feedback received on Investigational New Drug (IND) for ISLA-101 Phase 2a clinical study
- Island submitted response to FDA questions for ISLA-101 program (post quarter) following major body of work to draft protocol and identify potential partners for single ascending dose study
- Island closes the quarter with a cash position of $2.53m

MELBOURNE Australia, 27 April 2023: Australian mid-clinical stage antiviral drug development company, Island Pharmaceuticals Ltd (ASX: ILA; "Island"; "the Company") is pleased to release its Appendix 4C and quarterly business activities review for the three month period ended 31 March 2023 (Q3 FY23).

CEO of Island Pharmaceuticals, Dr David Foster said, *"Focus in the March quarter was on reviewing and responding to the US FDA's information requests on our ISLA-101 Investigational New Drug application. We now await either a further response from the FDA or an IND clearance within the 30 day mandatory review period from date of filing. In the meantime, we are working through remaining non-hold items. I'm grateful to our team and regulatory advisors for working at pace to be able to file our response earlier in April and look forward to updating the market on next steps in due course."*

On 20 January 2023 Island announced that it had received feedback following FDA review of the Investigational New Drug (IND) application submitted for its ISLA-101 Phase 2a PEACH[1] clinical trial. As part of the feedback, the FDA specified that amendments to the trial protocol may be required and support for, or modifications of, the proposed dosing schedule may be necessary. Island was also placed on Clinical Hold.

On 1 February 2023, Island announced it had received additional feedback. The FDA letter further clarified that amendments to the protocol and IND would be necessary to advance the program, as well as more data to support the proposed dosing regimen. Data will be obtained via a small single ascending dose clinical trial that measures blood concentration of ISLA-101, following administration-increasing doses of ISLA-101. The aim of the study is to ensure that administered doses could safely achieve blood concentrations of ISLA-101 that are predicated to be effective against the dengue virus. The Company anticipates that the study will be conducted in Australia, which will enable the trial expenses to be off-set by R&D tax credits.

Post quarter on 17 April 2023, Island formally filed its response after a review of all aspects of the original IND submission. As part of its response, Island completed a major body of work in drafting the protocol for the Single Ascending Dose study, and partners were identified to support the study, including a Clinical Research Organisation that can run it and an analytical laboratory to test and analyse blood samples collected. Island has expanded its access to pharmacokinetics and regulatory affairs expertise to increase the likelihood that planned responses will meet the FDA requirements in order to proceed. As part of this Bobbi Drais was appointed Senior Regulatory Consultant to support Island with next steps around its regulatory strategy for ISLA-101. Ms. Drais specialises in regulatory

[1] The PEACH study is a Phase 2a randomized, double blind, placebo-controlled study for the Prophylactic Examination of an Antiviral in a Dengue Challenge model

strategic management with more than 25 years of experience in the pharmaceutical industry.

**Pipeline development**

Island continues to explore pipeline development opportunities, with plans to capitalise on information from the previously commissioned third party analysis of viruses and antiviral needs (see March quarterly, dated 28 April 2022.) The Company regularly attends partnering conferences with an eye to identifying potentially complementary technologies that are consistent the strategies suggested by Island's Scientific Advisory Board (SAB).

**Financial Summary**

Island's cash position was A$2.53million as at 31 March 2023 (A$3.43million as at 31 December 2022). During the March 2023 quarter total cash operating outflows were approximately A$885,000 (A$417,000 in the prior quarter), the increase in costs is largely due to invoices received and paid in the quarter relating to work performed in the December 2022 quarter as the Company was preparing for its Phase 2a clinical trial.

A summary of the operating cashflows for the three months ending 31 March 2023, compared with the proposed use of funds in Year 2 (twelve months) of Island's Prospectus, dated 26 February 2021 is outlined below:

| | Y2 First 12 Months (A$) | Y2 Per Prospectus (A$) |
|---|---|---|
| Clinical, regulatory and implementation | 1,445,000 | 1,451,000 |
| IP research and development | 139,000 | 560,390 |
| Formulation development | - | 455,000 |
| Working capital and administration costs | 1,364,000 | 1,222,610 |
| Expenses of the offer costs | - | |

During the twelve month period ending 31 March 2023, overall spend was lower than estimated in the use of funds as set out in the Prospectus due to the initial clinical trial delays and being placed on Clinical Hold by the FDA. 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$178,000 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:

Dr Paul MacLeman
Executive Chairman
Island Pharmaceuticals Ltd
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**About Island Pharmaceuticals**

Island (ASX: ILA) is a clinical-stage drug repurposing company, developing 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 dengue fever and other mosquito (or vector) borne diseases. The Company is moving rapidly into clinical trials for 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 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** | **Quarter ended ("current quarter")** |
|---|---|
| 48 641 183 842 | 31 March 2023 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (9 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | - |
| 1.2 | Payments for | | |
| | (a) research and development | (534) | (1,256) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs | (70) | (242) |
| | (f) administration and corporate costs | (281) | (715) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 3 | 8 |
| 1.5 | Interest and other costs of finance paid | (3) | (7) |
| 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** | **(885)** | **(2,212)** |

| | | | |
|---|---|---|---|
| **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 | - | - |

| 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) | - | - |
| **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) | - | - |
| 3.2 | 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 | (54) | (126) |
| 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** | **(54)** | **(126)** |
| | | | |
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 3,433 | 4,787 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (885) | (2,212) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (9 months) $A'000 |
|---|---|---|---|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (54) | (126) |
| 4.5 | Effect of movement in exchange rates on cash held | 33 | 78 |
| **4.6** | **Cash and cash equivalents at end of period** | **2,527** | **2,527** |

| 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 | 2,527 | 3,433 |
| 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)** | **2,527** | **3,433** |

| 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 | 178 |
| 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 Director fees, salary and superannuation for the CEO/Managing Director, Executive Chair and Non-Executive directors.

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 | 54 | 54 |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | **54** | **54** |

| | | |
|---|---|---|
| 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.

Hunter Premium Finance for insurance policies at Flat Rate of 4.96%, loan is unsecured.

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (Item 1.9) | (885) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 2,527 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 2,527 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | **2.9** |

*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: 27 April 2023

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.