**30 January 2023**

# ASX Announcement
# December 2022 Quarterly Activity Report and Appendix 4C

- ISLA-101 drug product passed stability and conformity testing ahead of coming Phase 2a PEACH[1] clinical trial in Dengue fever
- Investigational Review Board approval received for PEACH study
- Investigational New Drug (IND) application submission to the United States Food and Drug Administration (US FDA) announced 28 December 2022
- IND progress pending FDA written feedback, expected 30 days from 20 January 2023
- Key Canadian patent granted for ISLA-101
- Island closed the quarter with a cash position ahead of expectation, of $3.43m

MELBOURNE Australia, 30 January 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 December 2022 (Q2 FY23).

CEO of Island Pharmaceuticals, Dr David Foster said, *"The December quarter was a highly productive one for the Island team. We met several major milestones which enabled the submission of our Investigational New Drug application for ISLA-101 to the US FDA in late December. In January during a meeting with the FDA, our IND submission was placed on Clinical Hold, pending written feedback. We are preparing now to work constructively through that feedback, once received."*

On 28 December 2022 Island announced that it had submitted its Investigational New Drug application to the US FDA for its ISLA-101 Phase 2a PEACH clinical trial. ISLA-101 is a well known drug candidate that is being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases.

An Investigational New Drug application is a request from a clinical study sponsor to obtain authorisation from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Island Is the sponsor for the PEACH study. Once the IND is submitted, Island must wait 30 calendar days before initiating any clinical trials. During this time, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Prior to the IND application submission, on 15 December 2022, Island announced that the ISLA-101 drug product manufactured for use in the coming PEACH trial had passed its critical accelerated stability milestone. To achieve the milestone, the ISLA-101 drug product was analysed following a 30-day period to determine stability. Achievement of this milestone provided a key piece of data, which underpinned the submission of the IND application. Earlier in the quarter (14 November 2022), Island announced that the completion of analytical testing on the capsules had confirmed excellent content uniformity (a measure of the consistency of the level of active ingredient in each of the capsules).

On 15 December 2022, Island announced that Institutional Review Board approval had

[1] The PEACH study is a Phase 2a randomized, double blind, placebo-controlled study for the **P**rophylactic **E**xamination of an **A**ntiviral in a Dengue **Ch**allenge model

been granted for the ISLA-101 Phase 2a PEACH clinical trial, to be undertaken at SUNY Upstate University in New York. Institutional Review Board approval in the United States is analogous to Human Research Ethics Committee (HREC) approval in Australia. It is an important regulatory requirement, necessary for trial commencement.

**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.) Island's Scientific Advisory Board (SAB) has met to discuss pipeline expansion opportunities. The SAB intends to prioritise viruses identified in this analysis to nominate as targets for investigation in the two previously announced research collaborations with Monash and Griffith Universities. In addition, other opportunities are being explored by the Company following recent partnering and investor meetings.

**Intellectual property**

On 16 November 2022, a key patent relating to the Company's lead drug candidate, ISLA-101, was granted by the Canadian Intellectual Property Office (CIPO).

The Canadian patent grant entitled "INHIBITION OF FLAVIVIRUSES OR CHIKUNGUNYA VIRUSES USING RETINOIC ACID ANALOGUES" was issued under Canadian Patent No 2945825 and has an expiration date of 16 April 2034. The patent covers a method of treating or preventing dengue virus or other mosquito borne virus infections with ISLA-101. Island has licensed the IP portfolio, generated by Monash University.

**Corporate summary**

On 15 December 2022, CEO Dr David Foster and Executive Chairman, Dr Paul MacLeman welcomed investors to an online webinar, where they provided an update on the status of the ISLA-101 clinical trial. A video recording of the webinar is available to interested investors, via the company's website, here.

Analyst Rosemary Cummins of MST Access published research updates on the ISLA-101 program. Copies of those research reports are available on the Island website.

In early December, Dr Paul MacLeman introduced Island and the ISLA-101 program to investors in Singapore. Island also presented in a number of other conference forums to highlight ISLA-101 and the potential for prevention and treatment of dengue fever, including the World Antiviral Congress in San Francisco (29 November 2022), and Share Café's Hidden Gems Webinar which is, attended by a mix of institutional and retail investors. Island's CEO, Dr David Foster, virtually attended the Pharma Meeting Brazil event from 19-21 October 2022, to give a detailed overview of the Company to potential pharmaceutical partners in the Latin American region.

Post the December quarter, Island's CEO attended the JP Morgan healthcare week in San Francisco. A series of meetings were held with potential partners and a mix of new and existing investors.

**Financial Summary**

Island's cash position was A$3.43million as at 31 December 2022 (A$3.99million as at 30 September 2022). During the December 2022 quarter total cash operating outflows were approximately A$471,000 (A$930,000 in the prior quarter), the decrease in costs are largely due to delayed receipt of invoices from third parties.

A summary of the operating cashflows for three months ending 31 December 2022 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 9 Months (A$)** | **Y2 Per Prospectus (A$)** |
|---|---|---|
| Clinical, regulatory and implementation | 1,024,000 | 1,451,000 |
| IP research and development | 16,000 | 560,390 |
| Formulation development | - | 455,000 |
| Working capital and administration costs | 1,023,000 | 1,222,610 |
| | 2,063,000 | 3,689,000 |

During the nine-month period ending 31 December 2022, overall spend was lower than estimated in the use of funds as set out in the Prospectus due to the delay of the clinical trial when compared to the estimated timing when the Prospectus was lodged. 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$137,000 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 mid-clinical-stage 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 dengue[2] 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 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 December 2022 |

| **Consolidated 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 | (143) | (722) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs | (74) | (174) |
| | (f) administration and corporate costs | (200) | (432) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 3 | 5 |
| 1.5 | Interest and other costs of finance paid | (3) | (4) |
| 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** | **(417)** | **(1,327)** |

| **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 (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) | - | - |
| 3.2 | 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) | (72) |
| 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)** | **(72)** |
| | | | |
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 3,994 | 4,787 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (417) | (1,327) |
| 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 (6 months) $A'000 |
|---|---|---|---|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (54) | (72) |
| 4.5 | Effect of movement in exchange rates on cash held | (90) | 45 |
| **4.6** | **Cash and cash equivalents at end of period** | **3,433** | **3,433** |

| 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 | 3,433 | 3,994 |
| 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)** | **3,433** | **3,994** |

| 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 | 137 |
| 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 | 114 | 114 |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | **114** | **114** |

| | | |
|---|---|---|
| 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) | (417) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 3,433 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 3,433 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | **8.2** |

*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: ..30 January 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.