

31 July 2023

ASX Announcement June 2023 Quarterly Activity Report and Appendix 4C

- Clinical Hold lifted and Investigational New Drug (IND) clearance received for the ISLA-101 clinical program by the US Food and Drug Administration (FDA)
- Approval follows Island's response to FDA questions, post major body of work to draft protocol and identify potential partners for single ascending dose study
- Participated in leading industry conferences, including Pharma Meeting Brazil and the 2023 Bio International Convention
- Island was the beneficiary of grant research support for expanded data analysis in the planned ISLA-101 Phase 2a human clinical trial (PEACH study) in dengue fever (post quarter)
- Island closes the quarter with a cash position of \$1.998m

MELBOURNE Australia, 31 July 2023: Australian 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 30 June 2023 (Q4 FY23).

CEO of Island Pharmaceuticals, Dr David Foster said, *"Following our preparation of a large body of work in the March quarter to submit a response to the FDA, we were extremely pleased to receive clearance for our IND in May. Since that time we have been focused on preparing for our ISLA-101 Single Ascending Dose study."*

"During the quarter we were also extremely grateful to receive additional funding support from The Research Foundation for the State University of New York (SUNY) and the Congressionally Directed Medical Research Programs (CDMRP) for our PEACH clinical trial. This additional funding will enable us to expand on the data generated from the trial and therefore gain a deeper understanding of dengue fever and transmission of arboviruses."

On 17 April 2023 Island formally filed its response to the FDA feedback on the IND for the ISLA-101 Phase 2a clinical study, following the trial being placed on Clinical Hold. As part of its response, Island developed a protocol for a Single Ascending Dose study, and partners were identified to support the study, including a Clinical Research Organisation and an analytical laboratory.

On 16 May 2023 Island announced that the FDA had lifted the clinical hold and IND clearance had been received for the ISLA-101 clinical program, thus allowing the Company to proceed with the Single Ascending Dose study. For this study, data will be obtained via a small single ascending dose clinical trial that measures blood concentration of ISLA-101, following administration of increasing doses. The aim of the study is to ensure that administered doses could safely achieve blood concentrations of ISLA-101 that are predicted to be effective against the dengue virus. The study will be conducted in Australia, which will enable the trial expenses to be fully off-set by R&D tax credits.

On 7 July 2023, Island announced newly acquired grant research support for the planned PEACH study in dengue fever. The grant was awarded to The Research Foundation for the State University of New York (SUNY), at Upstate Medical University in Syracuse, New York, which is partnering with Island to advance development of ISLA-101. The US\$1.3m Congressionally Directed Medical Research Programs (CDMRP) grant will support laboratory testing and data analysis during Island's planned clinical trial at SUNY. The trial will evaluate the effectiveness of ISLA-101 to treat dengue fever induced in the human



challenge model. The funding will enable Island to significantly expand on the data being generated during the trial, further characterising Island's intellectual property (IP).

Corporate & Partnering Activities

In May, Island announced the appointment of Senior Regulatory Consultant Bobbi Drais to support Island with the Company's regulatory strategy. Ms. Bobbi Drais has extensive experience in the pharmaceutical industry and specialises in regulatory strategic management. Her appointment has expanded Island's access to in-house pharmacokinetics and regulatory affairs expertise in support of the Company's ongoing FDA communications regulatory strategy.

During the past quarter, the Board discussed and approved a plan to explore acquisition or in-licensing of new drug candidates. The Board approved specific screening and scoring criteria for prospects based in part on the following criteria: 1) small molecule program; 2) anti-viral 3) eligible for a Priority Review Voucher 4) possible non-dilutive funding to support clinical studies.

On 23-26 May Island CEO and Managing Director, Dr David Foster participated in this year's Pharma Meeting Brazil, an event focused on partnering opportunities for the pharmaceutical and healthcare industries. Dr Foster met with regional pharmaceutical companies and potential sites for clinical trials that may be conducted in countries where dengue is endemic.

On 5-8 June, Island attended the Biotechnology Innovation Organization's 2023 BIO International Convention in Boston, which was attended by more than 20,000 leaders in biotechnology and science sectors. Dr. Foster conducted numerous meetings with potential investors and partners at the event.

In June, Island was delighted to hear that Non-Executive Director, Dr Anna Lavelle AM FTSE GAICD was awarded the prestigious Member of the Order of Australia (AM) in the King's Birthday Honours List in recognition of the outstanding contribution she has made to the life sciences sector.

Financial Summary

Island's cash position was A\$1.998million as at 30 June 2023 (A\$2.53million as at 31 March 2023). During the June 2023 quarter total cash operating outflows were approximately A\$486,000, a significant reduction from A\$885,000 in the prior quarter, as the Company focused on capital efficiencies while preparing for the upcoming dose escalation study.

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\$150,000 and included Director fees, salary and superannuation for the CEO/Managing Director, Executive Chair and NonExecutive Directors.

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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 dengue 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.

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command, in the amount of \$2,972,343 through the Peer Reviewed Medical Research Program under Award No. W81XWH-21-1-0800. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

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")

30 June 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(184)	(1,440)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(70)	(312)
(f) administration and corporate costs	(232)	(947)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	3	11
1.5 Interest and other costs of finance paid	(3)	(10)
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	(486)	(2,698)
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 (12 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)	(180)
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)	(180)
4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	2,527	4,787
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(486)	(2,698)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	-

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(54)	(180)
4.5	Effect of movement in exchange rates on cash held	11	89
4.6	Cash and cash equivalents at end of period	1,998	1,998

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	1,998	2,527
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)	1,998	2,527

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
150
-

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 Total financing facilities	-	-

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)	(486)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	1,998
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	1,998
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	4.1

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: 31 July 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.