

**28 October 2021**

## ASX Announcement

### **September 2021 Quarterly Activity Report and Appendix 4C**

- Key manufacturing agreement executed with Curia for synthesis of ISLA-101 clinical drug substance
- IND enabling activities continue, supported by Island's regulatory team
- Plans advance with SUNY Upstate Medical University for upcoming Phase 2a PEACH<sup>1</sup> clinical trial in dengue fever
- Research Collaboration agreement executed with Griffith University
- Island enters into agreement with Compounds Australia to access libraries of molecules that Griffith University and Monash University will screen for anti-viral activity under Research Collaboration Agreements
- Key ISLA-101 patent granted by IP Australia
- Island closed the quarter with a strong cash position of A\$6.26m.

MELBOURNE Australia, 28 October 2021: 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 30 September 2021 (Q1 FY22).

CEO of Island Pharmaceuticals, Dr David Foster said, *"We have had an exciting quarter and are happy to announce productive developments on several fronts. We have been in close communication with partners to advance our lead program, ISLA-101, to clinical trials. In addition to entering into an agreement with Curia to manufacture our clinical material, we have continued to engage with our partners to move forward with IND preparation and plans for the upcoming PEACH study to be conducted at SUNY Upstate. We have also entered into key agreements with Griffith University and Compounds Australia which will further enable our pipeline development."*

#### **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 enable 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

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<sup>1</sup> A Phase 2, Randomized, Double blind, Placebo-controlled Study for the Prophylactic Examination of an Antiviral in a Dengue Challenge Model



a potential preventative for dengue fever. The funds raised enable Island's drug repurposing strategy to develop at speed.

Island is 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.

Post-quarter, Island participated in a non-deal roadshow, primarily in the US and also participated in the virtual partnering conference Pharma Meeting Brazil & LATAM. CEO, Dr. David Foster, met with a number of regional pharmaceutical companies and consultants with pharmaceutical expertise in Latin America. In addition, Dr. Foster is also participating in AusBiotech Investment's partnering program in late October. Finally, Island has been invited to present at the Biotech Showcase as part of JP Morgan Healthcare week in January 2022.

### **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.

Through the quarter, Island announced it had entered into a manufacturing agreement with Curia, inc. to manufacture drug substance for its upcoming PEACH Phase 2a clinical trial.

Upon obtaining the final API (drug substance) which will be manufactured under Good Manufacturing Practice (GMP) conditions, the drug substance will be formulated into drug product for use in the upcoming Phase II clinical trial, which is on track to begin in Q1 of 2022.

Island is collaborating with the State University of New York (SUNY) Upstate in Syracuse for the ISLA-101 Phase II Clinical Trial. The Company has maintained frequent communication with collaborators at SUNY Upstate to continue planning for the dengue human infection model (DHIM) Phase 2 clinical trial and is currently working towards completion of a Clinical Trial agreement. An update on this agreement is expected shortly.

In addition, Island has been working with regulatory consultants to finalise its Investigational New Drug (IND) application, which will be submitted to the US Food and Drug Administration following completion of clinical product manufacturing.

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

Island continues to engage with its experienced Scientific Advisory Board (SAB). Through the quarter, the SAB met and discussed activities related to ISLA-101 and potential future product development.

An Australian patent grant for ISLA-101, entitled, "Method of Viral Inhibition" was issued on AUS Patent No **2019213440** and has an expiration date of 16 April 2034. Island has licensed the IP portfolio, generated by Monash University.

The grant of the US patent is a significant development for Island Pharmaceuticals. Mosquito borne viruses, such as dengue, Zika and others represent major unmet medical



needs throughout the world and about 3 billion people – or 40% of the world’s population – live in areas with a risk of dengue<sup>2</sup>.

### Financial Summary

Island’s cash position was A\$6.26million as at 30 September 2021. During the September 2021 quarter total cash operating outflows were approximately A\$0.305million (A\$0.938million in the prior quarter).

A summary of the operating cashflows for six months ending 30 September 2021 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 6 Months (A\$)	Y1 Per Prospectus (A\$)
<b>Clinical, regulatory and implementation</b>	6,000	2,027,000
<b>IP research and development</b>	23,000	139,000
<b>Formulation development</b>	-	-
<b>Working capital and administration costs</b>	983,000	1,195,000
<b>Expenses of the offer costs</b>	450,000	450,000
	<b>1,465,000</b>	<b>3,811,000</b>

During the six-month period ended September 2021, overall spend remained broadly in line with the estimated use of funds as set out in the Prospectus. 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.

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\$133,000 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  
Isla Pharmaceuticals

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### About Island Pharmaceuticals

Island is 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

<sup>2</sup> Source: <https://www.cdc.gov/dengue/index.html>



fever and other mosquito (or vector) borne diseases. The Company is advancing toward a Phase 2a clinical trial in dengue-infected subjects.

If ISLA-101 achieves FDA approval, and certain other criteria are met, Isla 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) would 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")**

30 September 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(6)	(6)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(63)	(63)
(f) administration and corporate costs	(236)	(236)
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>(305)</b>	<b>(305)</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 (3 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	6,461	6,461
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(305)	(305)
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 (3 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	106	106
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,262</b>	<b>6,262</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	6,262	6,461
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>6,262</b>	<b>6,461</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**

133

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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.

**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)	(305)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	6,262
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	6,262
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>20.5</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 October 2021

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.