

27 January 2022

ASX Announcement

December 2021 Quarterly Activity Report and Appendix 4C

- Teresa Byrne appointed Vice President Clinical Product Development
- Key agreements signed for Island's ISLA-101 Phase 2a dengue fever clinical trial with The Research Foundation for The State University of New York (SUNY) as trial site and with ICON for Clinical Trials Support Services
- Dr. Kristopher Paolino, MD appointed to lead study at SUNY as Principal Investigator
- ISLA-101 Drug Substance manufactured
- Island closed the guarter with a strong cash position of A\$5.83m.

MELBOURNE Australia, 27 January 2022: 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 2021 (Q2 FY22).

CEO of Island Pharmaceuticals, Dr David Foster said, "Several key agreements were executed through the quarter, necessary for progressing our PEACH¹ Phase 2a trial, where we are assessing ISLA-101 in dengue fever. We were delighted to announce Dr Kristopher Paolino as Principal Investigator on the study and also to appoint Teresa Byrne to the Island team as VP Clinical Product Development – Teresa will oversee the clinical development of ISLA-101 and our other pipeline programs.

We are also pleased to announce that manufacturing of our drug substance has reached a critical milestone. We remain on track to begin dosing patients early this calendar year."

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 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.

¹ A Phase 2, Randomized, Double blind, Placebo-controlled Study for the **P**rophylactic **E**xamination of an **A**ntiviral in a Dengue **C**hallenge Model



Through the quarter, Island held its inaugural Annual General Meeting, with all resolutions passed with votes in favour in excess of 95.8%. Island thanks those shareholders who attended and all those who voted.

Post-quarter, Ms. Teresa Byrne was appointed as Vice President Clinical Product Development. Teresa has been engaged to oversee clinical development of Isla-101 in the upcoming PEACH trial and other pipeline development programs. Teresa is an experienced Clinical Research Executive, with more than 20 years of pharmaceutical industry experience from the research bench to the clinic, and has experience in both large company settings such as big pharmaceutical companies as well as in smaller biotech companies and CRO organizations.

Teresa is a key addition to the team as Island builds out the support required to further develop ISLA-101 and pipeline development programs. In addition to overseeing the PEACH study, Teresa will support all of our programs in a variety of ways including establishment of quality and/or clinical operations structure and systems, general clinical and quality oversight, vendor management, qualification and oversight.

Also in January, Island participated in the Biotech Showcase as part of JP Morgan Healthcare week. Through this event, Island's CEO, Dr David Foster held a series of meetings with potential pharmaceutical partners and 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.

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.

To support the PEACH trial, through the quarter, Island signed a Clinical Trial Agreement with The Research Foundation for The State University of New York (SUNY) on behalf of Upstate Medical University, Syracuse NY, where the trial will be conducted, and where PEACH's control (untreated) arm viral challenge studies have already been completed.

It is anticipated that the Phase 2a clinical trial will begin dosing subjects in early 2022 and will take 8-12 months to complete. The trial may enrol up to 16 individuals.

Dr. Kristopher Paolino, MD has been appointed Principal Investigator on the trial.

Post the quarter, Island announced it had signed a key agreement with Clinical Research Organisation, ICON Government and Public Health Solutions, Inc. f/k/a Clinical Research Management, Inc. ("ICON GPHS"). ICON GPHS is a CRO with significant expertise in clinical trials, including the dengue human infection model (DHIM) that Island will be using in the PEACH study.

ICON has a solid professional history as a quality CRO and has worked in the field of dengue fever research in the past. This Agreement allows Island to continue moving forward with its Phase 2a trial preparations at a rapid pace.

Also post the quarter, Island announced that the Drug Substance for use in formulation of the final dose form in the PEACH study had been manufactured and manufacturing of the formulated Drug Product is expected to begin shortly.

In addition, Island has continued 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 Drug Product manufacturing.



Pipeline development and intellectual property

Through the quarter, a data driven analysis was completed, where Island reviewed a number of viruses with unmet needs, for which the Company may develop future products. Island and its experienced Scientific Advisory Board (SAB) will be prioritising the viruses identified in this analysis to select viruses to nominate as targets in the two previously announced research collaborations.

Financial Summary

Island's cash position was A\$5.83million as at 31 December 2021. During the December 2021 quarter total cash operating outflows were approximately A\$0.414million (A\$0.305million in the prior quarter).

A summary of the operating cashflows for six months ending 31 December 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 9 Months (A\$)	Y1 Per Prospectus (A\$)
Clinical, regulatory and implementation	191,000	2,027,000
IP research and development	29,000	139,000
Formulation development	-	-
Working capital and administration costs	1,209,000	1,195,000
Expenses of the offer costs	450,000	450,000
	1,879,000	3,811,000

During the 9-month period ended December 2021, overall spend is lower than the estimated use of funds as set out in the Prospectus largely due to the change in API supply and delayed receipt of invoices from third parties. The Company expects R&D expenditure to significantly increase in the coming quarters as the Company preparesfor 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\$149,000 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 info@islandpharmaceuticals.com

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About Island Pharmaceuticals

Island 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 dengue² 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, 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) 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 <u>www.islandpharmaceuticals.com</u> 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 2021	

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	(182)	(188)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(64)	(127)
	(f) administration and corporate costs	(168)	(404)
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)	-	-
1.9	Net cash from / (used in) operating activities	(414)	(719)

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	-	

ASX Listing Rules Appendix 4C (17/07/20)

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	-	-
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	-	-
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,262	6,461
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(414)	(719)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	(19)	87
4.6	Cash and cash equivalents at end of period	5,829	5,829

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	5,829	6,262
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)	5,829	6,262

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	149
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.	Note: the arranger Add note	cing facilities e term "facility" includes all forms of financing ments available to the entity. es as necessary for an understanding of the of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan fa	acilities	-	-
7.2	Credit	standby arrangements	-	-
7.3	Other ((please specify)	-	-
7.4	Total f	inancing facilities	-	-
7.5	Unuse	ed financing facilities available at qu	uarter end	-
7.6	rate, m facilitie	e in the box below a description of each naturity date and whether it is secured as have been entered into or are propo e a note providing details of those facil	or unsecured. If any add osed to be entered into af	itional financing
N/A				
8.		ated cash available for future op		\$A'000
8.1		Net cash from / (used in) operating activities (Item 1.9)		(414)
8.2		Cash and cash equivalents at quarter end (Item 4.6)		5,829
8.3	Unused finance facilities available at quarter end (Item 7.5)		-	
8.4	Total available funding (Item 8.2 + Item 8.3) 5,8			5,829
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)			14.1
		the entity has reported positive net operating ca r the estimated quarters of funding available mu		m 8.5 as "N/A". Otherwise, a
8.6	If Item	8.5 is less than 2 quarters, please pro	ovide answers to the follo	wing questions:
	8.6.1	Does the entity expect that it will concash flows for the time being and, if		level of net operating
	Answer: N/A			
	8.6.2	Has the entity taken any steps, or do cash to fund its operations and, if so believe that they will be successful?		
	Answe	r: N/A		
	8.6.3	Does the entity expect to be able to objectives and, if so, on what basis?		nd to meet its business
	Answe	r: N/A		

Compliance statement

- 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 January 2022

Authorised by: The Board of Island Pharmaceuticals Limited

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.
- 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.