

28 July 2022

ASX Announcement June 2022 Quarterly Activity Report and Appendix 4C

- Sofgen Pharmaceuticals (Sofgen) appointed for the supply of clinical trial study drug for Island's Phase 2a clinical trial of ISLA-101 In dengue fever
- Clinical material on track to be manufactured mid-August 2022
- Dr Amy Patick joined Island's Scientific Advisory Board (post quarter)
- Island closed the quarter with cash position in line with expectations, of A\$4.8m

MELBOURNE Australia, 28 July 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 30 June 2022 (Q4 FY22).

CEO of Island Pharmaceuticals, Dr David Foster said, *"Undoubtedly the most significant news of the June quarter was our manufacturing update, key to underpinning our coming ISLA-101 Phase 2a PEACH study in dengue fever."*

"We are very pleased to have engaged Sofgen as our manufacturing partner, and also with the progress that is being made in preparing to manufacture our clinical drug product in August. We expect the remainder of CY 2022 to be news-flow rich as we work toward filing our investigational new drug application for the PEACH study, leading to the study's start later this year."

ISLA-101 trial preparation

As has previously been announced, 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 are enabling Island to conduct a Phase 2a 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.

Since listing, the Company has been focused on executing on the structured delivery of its ISLA-101 clinical trial. 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 for its PEACH trial. 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.

As noted in our June manufacturing update, ISLA-101 clinical material is being manufactured in mid-August 2022 under a new proposal from Sofgen Pharmaceuticals. Once manufactured, the material will undergo 30-day stability studies and release testing after which the Investigational New Drug Application (IND) can be finalised and filed. This is an important step required before the PEACH clinical trial can commence.

Based on the new manufacturing agreement, it is expected that the Investigational New Drug application will be filed in October 2022, with the trial commencing in November 2022.



While the manufacturing site for Island's drug product is in Florida, leading soft gel manufacturer, Sofgen Pharmaceuticals also has a strong presence in Latin America. Given the prevalence of dengue fever in the region, which is anticipated to be a significant market for ISLA-101, this is expected to be of further benefit to Island and potential future partners.

Corporate summary

Island's CEO, Dr David Foster attended an invitation only summit focusing on "*Flaviviruses: Epidemiology, Pathogenesis, Immunology, and Countermeasure Development.*" Through the summit, leaders in the areas of mosquito borne diseases discussed recent scientific breakthroughs in Flavivirus research. Valuable conversations were had and connections made with key government, academic and industry experts.

Island also presented at the BIO International Conference in San Diego, CA, and attended over 40 meetings with potential partners and collaborators.

During May, Dr Foster participated in a virtual partnering conference, Pharma Meeting Brazil, where he conducted multiple meetings with potential Latin America partners as well as international pharmaceutical companies.

Executive Chairman, Dr Paul MacLeman presented at the Gold Coast Investment Showcase, also in June 2022.

Post quarter, it was announced that Dr Amy Patick had joined Island's Scientific Advisory Board (SAB), and that Dr Simon Tucker was stepping off the SAB.

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 anti-viral needs (see March quarterly, dated 28 April 2022.) Island's newly configured Scientific Advisory Board will prioritise viruses identified in this analysis to nominate as targets in the two previously announced research collaborations with Monash and Griffith Universities. In addition, other opportunities are being explored following active participation in the recent partnering and investor meetings.

Financial Summary

Island’s cash position was A\$4.79million as at 30 June 2022 (A\$5.31million as at 31 March 2022). During the June 2022 quarter, total cash operating outflows were approximately A\$716,000 (A\$442,000 in the prior quarter). The increase in cash outflows was largely due to R&D in relation to the challenge study and the preparation for the Phase II clinical study.

A summary of the operating cashflows for three months ending 30 June 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 3 Months (A\$)	Y2 Per Prospectus (A\$)
Clinical, regulatory and implementation	302,000	1,451,000
IP research and development	6,000	560,390
Formulation development	-	55,000
Working capital and administration costs	407,000	1,222,610
	715,000	3,689,000

During the three-month period ending 30 June 2022, overall spend was lower than estimated in the use of funds as set out in the Prospectus as a result of the delay in clinical material being manufactured (as announced on 15 June 2022). 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\$143,000 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:

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 Island
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About Island Pharmaceuticals

Island (ASX: ILA) 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, 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

48 641 183 842

Quarter ended ("current quarter")

30 June 2022

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	(302)	(694)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(64)	(255)
(f) administration and corporate costs	(350)	(928)
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	(716)	(1,877)
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	-	-
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	5,309	6,461
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(716)	(1,877)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	194	203
4.6	Cash and cash equivalents at end of period	4,787	4,787

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	4,787	5,309
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)	4,787	5,309

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**

143

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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.

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.

N/A

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(716)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	4,787
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	4,787
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	6.69

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 July 2022

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.