Island Pharmaceuticals

ILA.AX

MST Access
A research platform of MST Financial

08 April 2024

Data to confirm PEACH trial

NEED TO KNOW

- A$1.95m (net A$1.75m) funding allows for SAD** study data analysis
- SAD study data to confirm ISLA-101 dose(s) achieves effective drug blood concentration levels for its PEACH Phase 2a clinical trial and safety
- Dengue Fever presents as an increasing unmet clinical need

ILA's recent funding of A$1.95m (A$1.75m net) (32m shares at $0.06ps) will support analysis of the data from its SAD study. The study is designed to ensure the administered doses for its clinical trial program can achieve the blood concentration levels that are predicted to be effective against dengue fever.

The study's results are planned for early 2024. The data will inform discussions with FDA regarding the format of ILA's planned Phase2a PEACH clinical trial.

The PEACH trial will provide the first efficacy data - **a key valuation step**.

Investment Thesis

Clear unmet need: There is no effective Dengue Fever therapy and only limited use of preventative vaccines. ISLA-101 is believed to offer both preventative and therapeutic roles.

Expanding potential market: The United Nations described 2023 as a 'horror year', with the ongoing spread of the disease into southern EU and US/Central America.

ISLA-101 has the potential to be used in multiple indications: The mechanism of action of ISLA-101 also supports potential application in Yellow Fever virus, West Nile virus, Japanese encephalitis and Zika virus.

Valuation

MST's 12-month forward comparable company valuation of $0.11 from $0.19 previously primarily reflects the impact of the recent share and options issue. It is based on a comparable ASX listed companies approach. Confirmation by the FDA approval to commence the Phase 2a trial presents near term upside risk. MST also notes that data from the SAD study may allow for changes to the planned clinical program, potentially bringing savings, both of time and costs, to the ongoing trial program. MST presents Immuron (IMC.AX), as an example of the potential valuation upside on positive Phase 2a clinical data.

Risks

The valuation is subject to the usual drug development risks; regulatory approval, market entry, market size, market share, pricing, drug supply, competitor products, timing and potential licensing metrics – all may differ to MST assumptions, presenting upside/downside risk. MST notes, given the delay of the trial, its commencement may see some upside with positive trial results to see a re-rating of the stock.

**Prophylactic Examination of an Antiviral in a Dengue Challenge Model*

*** Single Ascending Dose*

Equity Research Australia

Pharmaceuticals, Biotechnology/Life Sciences

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ISLAND PHARMACEUTICALS
Antiviral therapeutics

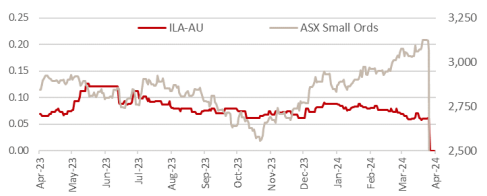
Island Pharmaceuticals is a drug research company, focused on repurposing drugs to prevent and/or treat viral illnesses. Repurposed drugs potentially offer shorter, lower cost routes to market and a higher probability of approval. ILA's first target is dengue infection. Its lead drug candidate, ISLA-101 (fenretinide), offers application in a number of other viral related illnesses. ILA aims to build a strong pipeline of drug candidates through in-licensing agreements and acquisition. www.islandpharmaceuticals.com

Valuation	**A$0.11** *(from A$0.19)*
Current price	**A$0.06**
Market cap	**A$6.9m**
Cash on hand	**eA$2.73m (post raise)**

Upcoming Catalysts / Next News

Period	
H1CY24	Read out of SAD study
CY24	Start Phase 2a trial

Share Price (A$)



Source: FactSet, MST Access

Report prepared by MST Access, a registered business name of MST Financial services ABN 617 475 180 AFSL 500 557.
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Figure 1: Financial Summary

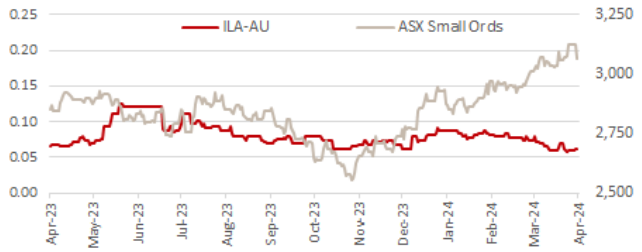
Island Pharmaceuticals Limited — ILA-AU

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.06**
52 week low / high	A$	0.139 - 0.055
Valuation (12 month forward)	**A$**	**0.11**
Market capitalisation	**A$m**	**6.9**
Shares on issue	m	113.8
Options	m	42.3
Other equity	m	75.0
Potential Shares on issue (diluted	m	231.1

12 month performance



INVESTMENT FUNDAMENTALS		FY22	FY23	FY24E	FY25E	FY26E
EPS Reported (undiluted)	¢	(3.2)	(3.5)	(3.0)	(1.6)	(1.3)
EPS Underlying (undiluted)	**¢**	**(3.2)**	**(3.5)**	**(3.0)**	**(1.6)**	**(1.3)**
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**	**-**

KEY RATIOS (A$)		FY22	FY23	FY24E	FY25E	FY26E
Forecast year end shares	m	81	81	114	164	189
Market cap (Y/E / Spot)	**$m**	**5.0**	**5.0**	**6.9**	**10.0**	**11.5**
Net debt /(cash)	$m	(4.8)	(1.4)	(0.6)	(3.1)	(5.6)
Enterprise value	**$m**	**0.2**	**3.6**	**6.4**	**6.8**	**5.9**
EV/Sales	x	n/a	n/a	n/a	n/a	n/a
EV/EBITDA	**x**	**(0.1)**	**(1.3)**	**(2.2)**	**(2.7)**	**(2.2)**
EV/EBIT	x	(0.1)	(1.3)	(2.2)	(2.7)	(2.2)
Net debt / Enterpprise Value	x	(28.2)	(0.4)	(0.1)	(0.5)	(0.9)
Gearing (net debt / EBITDA)	**x**	**1.8**	**0.5**	**0.2**	**1.2**	**2.1**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Price to operating cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow	**$m**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow per share	$	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Price to free cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow yield	**%**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Book value / share	$	0.05	0.01	0.01	0.02	0.03
Price to book (NAV)	**x**	**1.1**	**4.2**	**9.4**	**3.1**	**2.0**
NTA / share	$	0.05	0.01	0.01	0.02	0.03
Price to NTA	**x**	**1.1**	**4.2**	**9.4**	**3.1**	**2.0**
EBITDA margin	%	n/m	n/m	n/m	n/m	n/m
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	n/m	n/m	n/m

PROFIT AND LOSS (A$)		FY22	FY23	FY24E	FY25E	FY26E
Revenue & Other Income	$m	-	0.0	1.0	-	-
Expenses	$m	(2.6)	(2.8)	(3.8)	(2.6)	(2.6)
EBITDA	**$m**	**(2.6)**	**(2.8)**	**(2.9)**	**(2.6)**	**(2.6)**
D&A	$m	-	-	-	-	-
EBIT	**$m**	**(2.6)**	**(2.8)**	**(2.9)**	**(2.6)**	**(2.6)**
Interest	$m	-	(0.0)	(0.0)	-	0.1
Pre-tax Profit	**$m**	**(2.6)**	**(2.8)**	**(2.9)**	**(2.6)**	**(2.5)**
Tax	$m	-	-	-	-	-
Underlying NPAT	**$m**	**(2.6)**	**(2.8)**	**(2.9)**	**(2.6)**	**(2.5)**

BALANCE SHEET (A$)		FY22	FY23	FY24E	FY25E	FY26E
Cash	$m	4.8	1.4	1.1	3.1	5.6
Receivables	$m	0.0	0.0	0.6	-	-
Inventory	$m	-	-	-	-	-
PPE	$m	-	-	-	-	-
Other	$m	0.1	0.0	0.2	0.2	0.2
Total Assets	**$m**	**4.9**	**1.5**	**1.9**	**3.3**	**5.8**
Creditors	$m	0.5	0.2	0.6	-	-
Borrowings	$m	-	-	0.5	-	-
Other	$m	0.0	0.1	0.1	0.1	0.1
Total Liabilities	**$m**	**0.6**	**0.3**	**1.1**	**0.1**	**0.1**
Shareholder's equity	**$m**	**4.3**	**1.2**	**0.7**	**3.2**	**5.7**

CASH FLOW (A$)		FY22	FY23	FY24E	FY25E	FY26E
Receipts from customers	$m	-	-	-	-	-
Payments to suppliers and employe	$m	(1.9)	(2.7)	(3.5)	(2.6)	(2.6)
R&D rebate	$m	-	-	0.4	-	-
Milestones	$m	-	-	-	-	-
Interest	$m	-	0.0	(0.0)	-	0.1
Tax	$m	-	-	-	-	-
Other	$m	-	-	0.0	-	-
Operating cash flow	**$m**	**(1.9)**	**(2.7)**	**(3.1)**	**(2.6)**	**(2.5)**
Capex	$m	-	-	-	-	-
Acquisitions	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Investing cash flow	**$m**	**-**	**-**	**-**	**-**	**-**
Borrowings	$m	-	(0.2)	0.3	(0.4)	-
Equity	$m	-	-	1.8	5.0	5.0
Dividend	$m	-	-	-	-	-
Financing cash flow	**$m**	**-**	**(0.2)**	**2.1**	**4.6**	**5.0**
Change in Cash / FX	$m	(1.9)	(2.9)	(0.9)	2.1	2.5
Year end cash	**$m**	**4.8**	**2.0**	**1.1**	**3.1**	**5.6**

Source: ILA, MST assumptions

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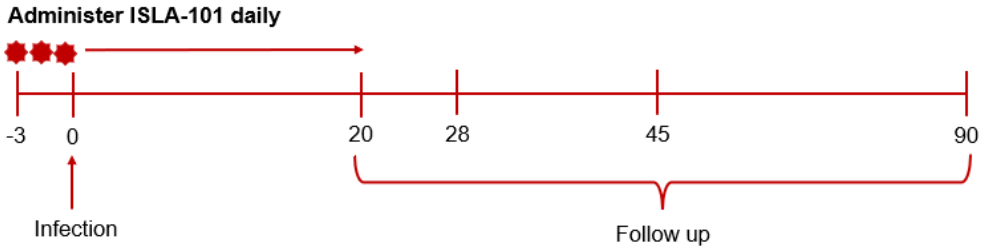
SAD study data to inform Phase 2a PEACH trial

ILA's ISLA-101, re-purposed fenretinide, is being trialed as a prophylactic (disease -preventing) therapy in Dengue Fever. The company's recent fund raising of $1.95m (net $1.75m) is planned to finance the analysis of the data from its Single Ascending Dose (SAD) study. The SAD study was undertaken over late CY23 to confirm that the administered doses of ISLA-101 could safely achieve the blood concentrations that were predicted to be effective against Dengue virus infection. The SAD results, planned for early CY24, will be used to inform discussions with the FDA regarding dosing for ILA's planned Phase 2a PEACH clinical trial.

Figure 2: Phase2a PEACH Trial Format



Inclusion

- Healthy Subjects
- Age 18 – 65
- Willing to use contraception for the duration of the study
- Informed consent

Primary endpoint

- Assess the prophylactic effect of ISLA-101 on fever, clinical symptoms, laboratory abnormalities and viremia after challenge with DENV-1-LVHC

Secondary endpoints

- Characterize the clinical, immunologic and virologic responses following ISLA 101 after challenge with DENV-1-LVHC
- Assess the safety of ISLA 101 in the challenge with DENV-1-LVHC

Source: ILA

The PEACH clinical trial is planned to be a randomized, double blind, placebo-controlled trial to investigate ISLA-101's prophylactic effects against dengue fever. Assessment will include the development of both clinical signs such as fever and laboratory measures of virologic responses following infection.

ILA plans to conduct the study using a Dengue Human Infection Model (DHIM), a challenge model. Challenge studies involve injecting healthy subjects with an attenuated (weakened) dengue virus and then studying the course of the infection and the effects on the study candidate in a controlled setting. Challenge trials generally offer a number of benefits:

- allow for faster timelines, as there is no need to wait for natural infection within the community enable stricter control over potential variables such as exposure to the virus
- require fewer subjects. thereby bringing lower
- stricter control of trial variables

As it continues its interactions with the FDA, ILA is working with its clinical trial partners to expedite the start of the trial on confirmation of the trial protocol.

Data to date

ISLA-101 has demonstrated significant antiviral effects in vitro and protective benefits in lethal animal studies. The studies reported a reduction in mortality by 70% among dengue and zika infected animals. Clinical data to date have reported that the drug was safe and well-tolerated across all doses. As a re- purposed drug, ISLA offers strong safety data. The PEACH study will provide the first data on efficacy in humans – a major milestone.

Additional funding

ILA's recent raising secured A$1.95m (A$1.75 net of fees) will be employed for analysis of Phase1 study and preparations for Phase 2a trial.

Figure 3: ILA funding allocations

Use of funds	A$000's
Completion and analysis of data from SAD study	507
Preparation for FDA discussions re Phase 2a PEACH clinical trial	246
Intellectual Property and licence fees	112
Ongoing business activities	887
Costs of raising	199
Total	**1,950**

Source: ILA

The fully underwritten non renounceable pro rata rights offered eligible shareholders;

- the right to acquire two shares for every five existing shares held 29.02.24 at 6 cents per share
- one new option (exercise price of 6 cents and expiry date 14.03.25) for every new share issued under the offer
- the right for option holder to be issued with additional options under the formula of one option for every new option exercised within 3 months of 14.03.24.

ILA has negotiated a loan facility with Radium Capital. The loan is based on its forecast FY24 Research and Development Tax Incentive (RDTI) refund. ILA received A$386.3K in December 2023. ILA will accrue R&D credits through the financial year as the company continues its R&D program. ILA's loan facility of A$118K at December 2023 is unsecured at a flat rate of 4.95%. Repayment is timed to co-incide with the receipt of ILA's FY24 RDTI refund, expected by November 2024.

Upcoming H2FY24 Milestones

- SAD trial readout
- FDA meeting to confirm PEACH Study protocol
- Commence PEACH trial
- Activities to support expansion of ILA's pipeline

Investment Thesis

In MST's view, ILA's approach offers a number of investment advantages. They include;

Drug Repurposing Strategy: Fenretinide, a re-purposed drug, offers safety data from 45+ clinical trials in cancer and other nonviral diseases. Safety accounts for some 30-45% of clinical trials failures. The existing data allows for reduced time, risk and cost – noting there are no clinical data to indicate its efficacy in viral illnesses.

Probability of Success: Review of drug approvals for therapies targeting infectious diseases demonstrates they carry a higher probability of approval. The average for all conditions of ~8% compares to ~13% for infectious diseases. [1]

Challenge Model Clinical Trial Design: ILA plans to conduct the study using a Dengue Human Infection Model (DHIM) or Challenge model. ILA's challenge studies involve injecting healthy subjects with an attenuated (weakened) dengue virus and then studying effects of the infection in a controlled setting. As discussed, challenge trials offer a number of benefits. to 'natural' infection. They include: fewer subjects, faster execution as there is no requirement to wait for natural infection and stricter control over trial variables.

P**otential Priority Review (PR) classification and Priority Review Voucher (PRV):** ISLA-101 candidate is potentially eligible to be awarded a Tropical Disease PRV. A Priority Review designation may be awarded for drugs that would significantly improve the treatment, diagnosis, or prevention of serious conditions. It allows for expedited review where the FDA aims to take action on an application for approval within six months, compared to 10 months under standard review. The key classification criteria include:

i) a drug or biological product for the prevention or treatment of a “tropical disease”

ii) meet the criteria for a priority review of application, as detailed above

iii) the drug contains no active ingredient that has been approved in any other

iv) clinical data to support approval of the therapy

PRVs may be sold. Current values of is ~US$100m as evidenced by Bluebird Bio which sold its PRV for US$102m in late 2022. [2] [3]

Expanding markets; Dengue is a major issue globally with up to 400m people infected each year, of which, 100m show symptoms and ~40,000 die. The United Nations Office for the Coordination of Humanitarian Affairs (OCHA) described 2023 as a horror year for dengue. with further expansion of the endemic areas. [4] [5] The current ~50% of the world’s population at risk of dengue is expected to continue to grow as global warming expands further into southern US, southern Europe and new parts of Africa.

Additional Markets; Preclinical studies support ISLA-101’s mechanism of action in a number of related viruses including Yellow Fever, West Nile and Japanese encephalitis and Chikungunya. ILA’s strategy for dengue can be leveraged for these diseases, offering the same advantages; faster timelines and cost efficiencies. The use of ISLA-101 in new indications has allowed for new patent filings that should offer market protection to 2034.

Highly Credentialled Partners; ILA’s approach is further supported by a retinue of noteworthy partners, US National Cancer Institute (NCI) and US Army. The ILA Board offers a depth of scientific and commercial expertise.

Valuation

Over CY22/CY23 ILA's planned clinical trial program experienced delays due to manufacturing issues and FDA enquiries regarding clinical trial protocol. In MST’s view, its valuation reflects the uncertainty that arose and delay to the planned start of the trial program. Completion of the SAD trial and confirmation of the commencement of its PEACH trial are likely to build investor confidence. MST’s 12-month forward comparable company valuation of $0.11 from $0.19 previously, primarily reflects the impact of the recent share and options issue. Confirmation by the FDA for the Phase 2a trial to commence presents near term upside risk. MST also notes that data from the SAD study may allow for changes to the planned clinical program, potentially bringing time savings and reduced costs to the ongoing trial program. MST’s forward valuation of A$26m is based on comparable ASX listed biotech companies at a similar stage. MST presents Immuron (IMC.AX), as an example of the potential valuation upside on positive Phase 2a clinical data.

Immuron IMC.AX a comparator

MST presents Immuron Ltd (IMC.AX, NASDAQ:IMRN, IMRNW) as an indicator of ILA's potential value on positive PEACH Phase 2a data. IMC shares a number of characteristics;

Disease targets; Both companies are targeting pathogen based infectious diseases. IMC has developed oral antibody therapies for a number of gastrointestinal (“GI”) tract infections, while ILA is targeting dengue fever, a viral systemic disease - noting dengue fever presents as significant unmet need with a high fatality rate without a specific treatment.

Stage of development; IMC offers a more advanced program with approvals of two over- the- counter products, Travelan® and Protectyn®. Travelan® was first approved in 2004 in Australia. Both are listed medicines on the Australian Register for Therapeutic Goods with indications to reduce the risk of travelers’ diarrhea and minor gastro-intestinal disorders. Travelan® is also listed in Canada where it is licensed as a natural health product to reduce the risk of travelers’ diarrhea and in the US as a dietary supplement for digestive tract protection.

Potential markets; Both companies are focused on 'travellers' including military personnel, business and recreational travelers to lesser developed areas. While, IMC's potential markets by area size are more extensive than ILA's, MST notes that dengue fever is endemic in large, densely populated areas. Global warming and other factors are resulting in expanding dengue-prevalent areas. Prior to 1970, there were only nine countries which experienced severe dengue epidemics. This compares to the disease now endemic in over 100 countries. From a comparative valuation viewpoint, in MST's view, while IMC's potential 'catchment' areas may be more extensive, the severity of dengue fever offers a higher clinical need that will drive strong uptake. From a market competition stance, MST also notes there is no approved preventative nor treatment for dengue fever. There are a number of therapies for gastrointestinal conditions such as 'travellers diarrhoea'.

Quality of partners; Both companies offer well credentialled partners, including the US Department of Defense. ILA has partnered with the US Army Medical Research and Materiel Command (USAMRMC) and will use its Dengue Human Infection Model (DHIM) at the State University New York (SUNY) Upstate Medical University. It has a Cooperative Research and Development Agreement (CRADA) with the US Army Medical Materiel Development Activity (USAMMDA). Under the CRADA, ILA gains access to the attenuated dengue virus and supporting data. SUNY will conduct the trial.

IMC provides insight to ILA's valuation

Review of **I**MC's share performance reflects a number of disappointments to the investor market over the years. In MST's view, the key driver of its current valuation of $28m, is its current FDA clinical trial program. In March 2024, positive Phase 2 data of Travelan® saw an ~80% increase in share price.

Over CY22/CY23 ILA's planned clinical trial program experienced a number of delays due to manufacturing issues and FDA enquiries regarding clinical trial protocol. In MST's view, its valuation reflects a discount from the uncertainty that has arisen and delay to the planned start of the trial program. Completion of the SAD trial and confirmation of the commencement of its PEACH trial are likely to start to re-build investor confidence. Positive clinical data to emerge from Phase 2a PEACH trial are likely to see a re-rating of the stock. MST's valuation of $24m is based on a comparable model. The valuation also acknowledges that as a repurposed drug, ISLA-101 offers strong safety data from over 45 previous clinical trials.

MST notes that there are upside/downside risks and sensitivities of drug development; clinical trial patient recruitment, timing and costs, regulatory approval and market entry, pricing, market penetration and sales, competitor drugs and potential royalties/licensing payments.

References

[1] Clinical Development Success Rates Contributing Factors 2011-2020 Biotechnology Innovation Organisation et al

[2]https://www.businesswire.com/news/home/20221130005434/en/bluebird-bio-Sells-Priority-Review-Voucher-for-102-Million

[3] https://ir.krystalbio.com/news-releases/news-release-details/krystal-biotech-announces-sale-priority-review-voucher-100

[4] https://reliefweb.int/report/world/dengue-fever-least-5-million-cases-and-5500-deaths-horror-year

[5]https://www.reuters.com/business/healthcare-pharmaceuticals/dengue-will-take-off-southern-europe-us-africa-this-decade-who-scientist-says-2023-10-06/

Personal disclosures

Rosemary Cummins received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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The companies and securities mentioned in this report, include:

Island Pharmaceuticals (ILA.AX) | Price A$0.06 | Target price A$0.11 | Recommendation -;

Price, target price and rating as at 08 April 2024 (not covered)*

Additional disclosures

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