Island Pharmaceuticals

ILA.AX

A research platform of MST Financial

20 November 2023

Clinical program starts

NEED TO KNOW

- Screening for SAD[1] clinical study commences
- SAD study to further optimise trial protocol
- Cash at Sep 30, 2023 was A$1.4m

ILA ISLA-101 has announced that screening of subjects for the ISLA-101 Single Ascending Dose (SAD) clinical study has commenced. The study aims to establish that the administered doses can safely achieve blood concentrations of ISLA-101 which are predicted to be effective against the dengue virus.

Broadened expertise/ tax advantage: ILA has engaged an Australian clinical trials facility and a Clinical Research Organisation (CRO) to run and monitor the SAD study. The CRO brings additional expertise and as an Australian-based clinical trial, it entitles ILA to a 43.5% R&D tax rebate.

Cash at Q1FY24 was A$1.4m.

Investment Thesis

Repurposed drugs offer significant advantages: In comparison to the development of 'first in human' drugs, ILA is repurposing drugs for viral illnesses. The strategy brings potential advantages including lower development costs, faster timelines and lower safety risk.

No approved treatment for Dengue Fever: The first FDA approved Dengue Fever drug may be eligible for a Priority Review Voucher, with a current value of ~US$100m.

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

Valuation

MST's 12-month forward valuation of A$26m, $0.19ps (prev A$22m, $0.18ps), is based on the average market capitalisation of a cohort of ASX-listed biotechnology companies in Phase 1/2 trials, a similar stage of development. Upside risk presents with FDA confirmation for the commencement of the Phase 2a trial. MST also notes that data from the SAD study may allow for adaption of the planned clinical program potentially bringing time savings and reduced costs.

Risks, Sensitivities

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 realisation of the valuation over the short term will be difficult but expects positive trial results in FY24 to see a re-rating of the stock.

Equities Research Australia

Biotechnology & Plasma Products

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ISLAND PHARMACEUTICALS
Antiviral therapeutics

ASX listed Island Pharmaceuticals (ILA.AX) 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.

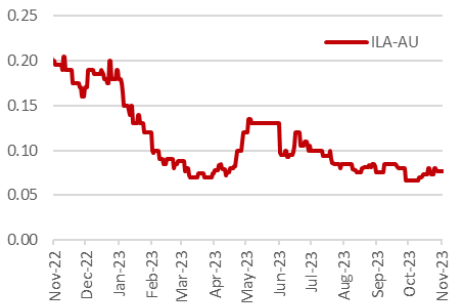
www.islandpharmaceuticals.com

Valuation	**A$0.19** (prev A$0.18)
Current price	**A$0.08**
Market cap	**A$6.3m**
Cash on hand	**A$1.4m** at Sep CY23 end

Potential Upcoming Catalysts and Newsflow

Period	
FY24	1st Subject enrolled in SAD Trial
FY24	SAD Trial results
FY24	FDA meeting on PEACH trial protocol

Share Price (A$)



Source: FactSet, MST Access

[1] Single Ascending Dose

Figure 1: Financial Summary

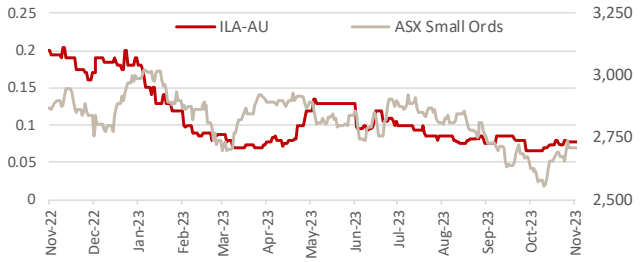
Island Pharmaceuticals Limited — ILA-AU

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.08**
52 week low / high	A$	0.06 - 0.21
Valuation (12 month forward)	**A$**	**0.19**
Market capitalisation	**A$m**	**6.3**
Shares on issue	m	81.3
Options	m	14.4
Other equity	m	40.0
Potential Shares on issue (diluted)	m	135.7

12 month performance



INVESTMENT FUNDAMENTALS		FY22	FY23	FY24E	FY25E	FY26E
EPS Reported (undiluted)	¢	(3.2)	(3.5)	(3.1)	(2.5)	(2.2)
EPS Underlying (undiluted)	**¢**	**(3.2)**	**(3.5)**	**(3.1)**	**(2.5)**	**(2.2)**
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$)		FY22	FY23	FY24E	FY25E	FY26E
Forecast year end shares	m	81	81	106	106	121
Market cap (Y/E / Spot)	**$m**	**6.5**	**6.5**	**8.5**	**8.5**	**9.7**
Net debt /(cash)	$m	(4.8)	(1.4)	(3.7)	(1.1)	(3.5)
Enterprise value	**$m**	**1.7**	**5.1**	**4.8**	**7.4**	**6.2**
EV/Sales	x	n/a	n/a	n/a	n/a	n/a
EV/EBITDA	**x**	**(0.7)**	**(1.8)**	**(1.5)**	**(2.8)**	**(2.3)**
EV/EBIT	x	(0.7)	(1.8)	(1.5)	(2.8)	(2.3)
Net debt / Enterpprise Value	x	(2.8)	(0.3)	(0.8)	(0.1)	(0.6)
Gearing (net debt / EBITDA)	**x**	**1.8**	**0.5**	**1.1**	**0.4**	**1.3**
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	0.03	0.01	0.03
Price to book (NAV)	**x**	**1.5**	**5.5**	**2.4**	**7.9**	**2.8**
NTA / share	$	0.05	0.01	0.03	0.01	0.03
Price to NTA	**x**	**1.5**	**5.5**	**2.4**	**7.9**	**2.8**
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	0.4	-	-
Expenses	$m	(2.6)	(2.8)	(3.7)	(2.6)	(2.7)
EBITDA	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.7)**
D&A	$m	-	-	-	-	-
EBIT	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.7)**
Interest	$m	-	(0.0)	-	-	0.1
Pre-tax Profit	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.6)**
Tax	$m	-	-	-	-	-
Underlying NPAT	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.6)**

BALANCE SHEET (A$)		FY22	FY23	FY24E	FY25E	FY26E
Cash	$m	4.8	1.4	3.7	1.1	3.5
Receivables	$m	0.0	0.0	0.0	-	-
Inventory	$m	-	-	-	-	-
PPE	$m	-	-	-	-	-
Other	$m	0.1	0.0	0.0	0.0	0.0
Total Assets	**$m**	**4.9**	**1.5**	**3.8**	**1.1**	**3.5**
Creditors	$m	0.5	0.2	0.2	-	-
Borrowings	$m	-	-	-	-	-
Other	$m	0.0	0.1	0.1	0.1	0.1
Total Liabilities	**$m**	**0.6**	**0.3**	**0.3**	**0.1**	**0.1**
Shareholder's equity	**$m**	**4.3**	**1.2**	**3.5**	**1.1**	**3.5**

CASH FLOW (A$)		FY22	FY23	FY24E	FY25E	FY26E
Receipts from customers	$m	-	-	-	-	-
Payments to suppliers and employee	$m	(1.9)	(2.7)	(3.7)	(2.6)	(2.7)
R&D rebate	$m	-	-	0.4	-	-
Milestones	$m	-	-	-	-	-
Interest	$m	-	0.0	-	-	0.1
Tax	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Operating cash flow	**$m**	**(1.9)**	**(2.7)**	**(3.3)**	**(2.6)**	**(2.6)**
Capex	$m	-	-	-	-	-
Acquisitions	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Investing cash flow	**$m**	**-**	**-**	**-**	**-**	**-**
Borrowings	$m	-	(0.2)	-	-	-
Equity	$m	-	-	5.0	-	5.0
Dividend	$m	-	-	-	-	-
Financing cash flow	**$m**	**-**	**(0.2)**	**5.0**	**-**	**5.0**
Change in Cash / FX	$m	(1.9)	(2.9)	1.7	(2.6)	2.4
Year end cash	**$m**	**4.8**	**2.0**	**3.7**	**1.1**	**3.5**

Source: MST, Company Reports

Screening of subjects for Single Ascending Dose starts

Island Pharmaceuticals Ltd (ASX: ILA) has announced that screening of subjects for the ISLA-101 Single Ascending Dose study has formally commenced. The announcement follows news on November 7 2023, that ILA had received Human Research Ethics Committee approval for Single Ascending Dose Study and in May 2023, US FDA trial approval.

The Single Ascending Dose study aims to establish that the administered doses can safely achieve blood concentrations of ISLA-101 which are predicted to be effective against the dengue virus. ILA has appointed Scientia Clinical Research, an Australian clinical trials facility and Beyond Drug Development, a Contract Research Organisation to conduct the study. The trial is being undertaken in Sydney (NSW). The undertaking of the trial in Australia allows for ILA to fully leverage Australia's Research & Development Tax Incentive scheme. The scheme allows for a 43.5% R&D tax rebate on expenses incurred in Australia, such as those relating to ILA's Contract Research Organisation, Beyond Drug Development and the clinical site, Scientia.

The SAD study will be a dose escalation study with 3 cohorts of increasing dose levels of ISLA-101 under fasted conditions. The third cohort will also be dosed following a meal, or in a "fed" condition, to explore any food effect of ISLA-101. A Safety Review Committee will review each cohort's data to determine if it is safe to move to the next cohort with a higher dose. The trial is expected to commence dosing in CY23, with read out of the trial results to follow in early CY24.

On confirmation of the dose, ILA may revise the protocol and seek input from the FDA as needed on the PEACH 2a trial, a human dengue challenge trial.

Investment Thesis

The investment thesis for ILA is built around its drug repurposing strategy. Its strategy offers reduced time, risk and cost. Its first target, fenretinide in dengue fever, highlights the advantages of its strategy.

Repurposed drugs offer:

1. Lower risk: As a later-stage asset, preparing for its Phase 2a trial ILA offers lower risk. As a re-purposed drug, ISLA-101 (fenretinide) offers data from 45+ clinical trials that support its safety in cancer and other nonviral diseases. Safety accounts for some 30-45% of clinical trial failures.
2. Review of drug approvals demonstrates that drugs targeting infectious diseases carry a higher probability of approval. The average for all conditions is ~8% which is in contrast to ~13% for infectious diseases[2].

ILA's fenretinide offers additional advantages:

3. 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 in these diseases, offering the same advantages; faster timelines and cost efficiencies.
4. The use of ISLA-101 in new indications has allowed for new patent filings that should offer market protection to 2034.
5. From a competitive perspective, there are no approved treatments for its first target, dengue fever. Dengvaxia®, a preventative vaccine, carries a number of serious adverse effects that have significantly restricted its use. More recently, Takeda (NYSE:TAK) voluntarily withdrew its FDA Biologics Licence Application (BLA) for its dengue fever vaccine candidate. Noting the clinical need and potential commercial reward see a number of treatment and preventative candidate therapies in development.
6. The wide geographic and populous areas endemic to dengue fever offer large markets – acknowledging the socioeconomic factors present a trade-off of price and market uptake. Environmental factors are contributing to an expansion of dengue fever prevalent areas. Encroachment into developed countries may bring change to the current market dynamics. Outbreaks of Zika Virus in the southern US were recorded in 2018/19. In 2022, deaths from the Japanese Encephalitis Virus outbreak occurred in Australia in areas not previously associated with the disease.

[2] Clinical Development Success Rates and Contributing Factors 2011-2020

7. The credibility of ILA's approach is further supported by a retinue of noteworthy partners, US National Cancer Institute (NCI) and the US Army and Camargo Pharmaceutical Services. The ILA Board offers a depth of scientific and commercial expertise.

Valuation, Risks, Sensitivities

MST's valuation is based on the average market capitalisation of a cohort of ASX-listed biotechs in Phase 1/2 trial, a similar stage of development to ISLA-101. In MST's view, there is rationale for a premium to the Phase 1/2 cohort. Phase 1 and 2 trials focus on safety with early indications of efficacy often included in the Phase 2. As a repurposed drug, ISLA-101 offers strong safety data from over 45 previous clinical trials.

MST's peer-based valuation of $26m, $0.19ps (prev A$25m, A$0.18ps) compares to a current market capitalisation of A$6.3m. In MST's view, the discount reflects the uncertainty that has arisen from the FDA enquiries and delay to the planned start of the trial program. It is positive that the clinical trial program has commenced. Further progress and confirmation of the PEACH trial are likely to build investor confidence. MST also notes that the general biotech market trends have also been challenging, with risk-averse investors shying from the sector.

Upside/downside risks and sensitivities of drug development include clinical trial patient recruitment, timing and costs, regulatory approval and market entry, pricing, market penetration and sales, competitor drugs and potential royalties/licensing payments.

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