Island Pharmaceuticals

ILA.AX

MST Access

A research platform of MST Financial

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Clinical program to start

NEED TO KNOW

- FDA clearance to begin SAD[1] clinical study
- SAD study to further optimise trial protocol
- ILA is repurposing drugs – lower safety risk

ILA's ISLA-101 receives FDA clearance for SAD clinical study: The FDA has lifted its clinical hold and granted ILA an Investigational New Drug (IND) clearance for the company to undertake a Single Ascending Dose (SAD) study. Hospital Research Ethics Committee (HREC) approval is also required.

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, ILA is entitled to a 43.5% R&D tax rebate.

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 Priority Review Voucher, with 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$22m, (previously $29m) 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 from 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.

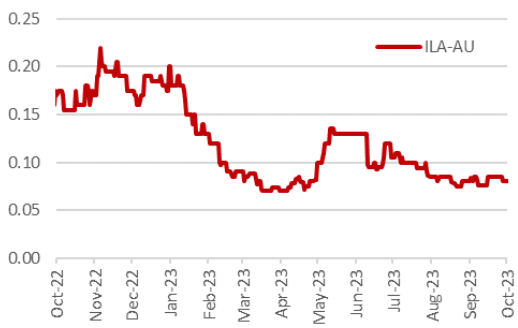
www.islandpharmaceuticals.com

Valuation	**A$0.18ps** (prev $0.36)
Current price	**A$0.08ps**
Market cap	**A$6.7m**
Cash on hand	**A$2.0m** at FY23 end

Upcoming Catalysts and Newsflow

Period	
FY24	1st Subject enrolled in SAD
FY24	SAD results
FY24	Confirmation/commencement Phase 2a trial

Share Price (A$)



Source: FactSet, MST Access

[1] Single Ascending Dose

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Figure 1: Financial Summary

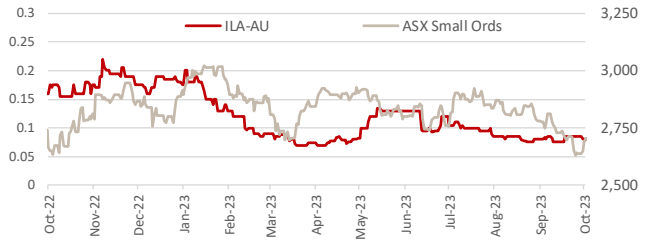
Island Pharmaceuticals Limited — ILA-AU

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.08**
52 week low / high	A$	0.25-0.07
Valuation (12 month forward)	**A$**	**0.18**
Market capitalisation	**A$m**	**6.7**
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)	(3.5)	(2.5)	(2.2)
EPS Underlying (undiluted)	**¢**	**(3.2)**	**(3.5)**	**(3.5)**	**(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)	$m	(4.8)	(2.0)	(3.3)	(0.7)	(3.1)
Enterprise value	**$m**	**1.7**	**4.5**	**5.2**	**7.8**	**6.6**
EV/Sales	x	n/a	n/a	n/a	n/a	n/a
EV/EBITDA	**x**	**(0.7)**	**(1.6)**	**(1.4)**	**(3.0)**	**(2.5)**
EV/EBIT	x	(0.7)	(1.6)	(1.4)	(3.0)	(2.5)
Net debt / Enterpprise Value	x	(2.8)	(0.4)	(0.6)	(0.1)	(0.5)
Gearing (net debt / EBITDA)	**x**	**1.8**	**0.7**	**0.9**	**0.3**	**1.2**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Price to operating cash flow	**x**	**(3.5)**	**(2.4)**	**(2.3)**	**(3.3)**	**(3.7)**
Free cash flow	**$m**	**(1.9)**	**(2.7)**	**(3.7)**	**(2.6)**	**(2.6)**
Free cash flow per share	$	(0.02)	(0.03)	(0.03)	(0.02)	(0.02)
Price to free cash flow	**x**	**(3.5)**	**(2.4)**	**(2.3)**	**(3.3)**	**(3.7)**
Free cash flow yield	**%**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Book value / share	$	0.05	0.02	0.03	0.01	0.03
Price to book (NAV)	**x**	**1.5**	**3.6**	**2.7**	**12.2**	**3.2**
NTA / share	$	0.05	0.02	0.03	0.01	0.03
Price to NTA	**x**	**1.5**	**3.6**	**2.7**	**12.2**	**3.2**
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	-	-	-
Expenses	$m	(2.6)	(2.8)	(3.7)	(2.6)	(2.7)
EBITDA	**$m**	**(2.6)**	**(2.8)**	**(3.7)**	**(2.6)**	**(2.7)**
D&A	$m	-	-	-	-	-
EBIT	**$m**	**(2.6)**	**(2.8)**	**(3.7)**	**(2.6)**	**(2.7)**
Interest	$m	-	(0.0)	-	-	0.1
Pre-tax Profit	**$m**	**(2.6)**	**(2.8)**	**(3.7)**	**(2.6)**	**(2.6)**
Tax	$m	-	-	-	-	-
Underlying NPAT	**$m**	**(2.6)**	**(2.8)**	**(3.7)**	**(2.6)**	**(2.6)**

BALANCE SHEET (A$)		FY22	FY23	FY24E	FY25E	FY26E
Cash	$m	4.8	2.0	3.3	0.7	3.1
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**	**2.0**	**3.4**	**0.7**	**3.1**
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**	**1.8**	**3.1**	**0.7**	**3.1**

CASH FLOW (A$)		FY22	FY23	FY24E	FY25E	FY26E
Receipts from customers	$m	-	-	-	-	-
Payments to suppliers and employees	$m	(1.9)	(2.7)	(3.7)	(2.6)	(2.7)
R&D rebate	$m	-	-	-	-	-
Milestones	$m	-	-	-	-	-
Interest	$m	-	0.0	-	-	0.1
Tax	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Operating cash flow	**$m**	**(1.9)**	**(2.7)**	**(3.7)**	**(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	$m	(1.9)	(2.9)	1.3	(2.6)	2.4
Year end cash	**$m**	**4.8**	**2.0**	**3.3**	**0.7**	**3.1**

Source: MST, Company Reports

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Phase 2 trial Update

- In December 2022, ILA submitted its Investigational New Drug application to the US FDA for approval to commence its Phase 2a trial.
- In January 2023, the FDA raised a number of queries and placed a clinical hold on the trial.
- In February 2023, the FDA provided further detail and requested that Island Pharmaceuticals (ILA) undertake a Single Ascending Dose (SAD) trial. The SAD trial will progressively measure the blood concentration levels of ISLA-101, following administration of increasing doses. The aim is to ensure the dose for the Phase 2a trial will achieve the blood concentration levels that are predicted to be effective against the dengue virus.
- In April 2023, ILA filed its response to the FDA after a review of all aspects of the original IND submission.
- In May 2023, ILA announced that the FDA had lifted the clinical hold and granted an Investigational New Drug approval for the SAD trial. The Phase 2a trial is planned to follow on dose confirmation.
- In September 2023, ILA announced that its preparatory work was essentially completed and that it plans to start the SAD trial in October, pending HREC approval.

Clinical trial program to start on confirmation of dose

Data from the SAD study that identifies the effective dosing range may allow for the number of cohorts to be reduced. It would offer both cost and time savings.

ILA has announced that it plans to start the clinical trial program of its repurposed drug, ISLA-101 (fenretinide) in October, subject to Hospital Research Ethics Committee approval. The trial program was placed on a 'Clinical Hold' in January 2023, when the FDA raised queries regarding the trial design. The revised trial program includes a SAD study.

ILA plans to undertake a human challenge trial, whereby the subjects are exposed to the dengue fever pathogen. A key concern is the exposure of a 'healthy' subject to a potentially serious disease. The SAD study aims to confirm that administered doses will achieve an efficacious level of the drug in the blood. ILA has determined the dosing formula based on its own research and previous preclinical/ clinical data. As a repurposed drug, the resources are deep with data relating to safety and dosing available from over 45 ISLA-101/fenretinide trials in diseases including cancer, macular degeneration and Cystic Fibrosis.

The SAD study will be a dose escalation study with four cohorts of increasing dose levels. The 'starting' dose will be increased until the blood concentrations of ISLA-101 reach the pre-determined level, referred to as the Maximum Tolerated Dose (MTD). 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 complete dosing in late CY23, with read out of the trial results to follow in early CY24.

On confirmation of the dose, ILA will seek regulatory approval to commence its PEACH2a trial, also a human dengue challenge trial. ILA has appointed Scientia Clinical Research, an Australian clinical trials facility and Beyond Drug Development, a Contract Research Organisation to conduct the study. 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.

Impact for ILA

ILA had planned to start its Phase 2a trial in H2FY22 with results planned for H1FY23. Regulatory queries have brought significant delays with additional costs and longer lead time to potential revenue flows. From a financial perspective, ILA reported cash of ~ $2m at FY23 end.

MST notes that there have been changes to the competitive landscape over this period. The unmet medical need attracts strong interest. A number of prospective therapies including both preventative vaccines and therapeutics have been withdrawn over the recent period.

Reduced competition increases the odds for a possible Priority Review Voucher.

In addition to reducing potential competitors in the marketplace, the smaller competitive field increases the chance of being the first to market. As a tropical disease for which there is no treatment, dengue fever is an FDA-designated Neglected Tropical Disease. As such if ISLA-101 is the first approved treatment in dengue fever by the FDA and it receives a Priority Review, ILA will qualify for a Priority Review Voucher (PRV). PRVs are awarded to pharmaceutical companies for the development and approval of drugs in nominated diseases. The voucher can be used for future drugs that do not meet the qualifying criteria or sold with current estimated pricing of ~US$100m.

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Valuation, Risks, Sensitivities

Figure 2: Cohort of ASX-listed biotechs in Phase 1/2 trial

Company	ASX Ticker	Market Cap ($m)	Current Phase
Adalta Ltd	1AD-AU	9.3	Completed Phase I trial and starting Phase 2
Chimeric Therapeutics	CHM-AU	13.9	Completed Phase I trial and starting Phase 2
Prescient Therapeutics Ltd	PTX-AU	44.2	Completed Phase I trial and starting Phase 2
PharmAust Limited	PAA-AU	26.9	Ongoing Phase 2 trial
Amplia Therapeutics Ltd	ATX-AU	15.7	Ongoing Phase 2 trial
Actinogen Medical	ACW-AU	44.3	Ongoing Phase 2 trials
Noxopharm	NOX-AU	26.3	Ongoing Phase 2 trials
Immuron Ltd	IMC-AU	17.3	Ongoing Phase 2 trials
Alterity Therapeutics Ltd	ATH-AU	17.1	Ongoing Phase 2 trials
Recce Pharmaceuticals	RCE-AU	89.3	Ongoing Phase 2 trials
KAZIA Therapeutics Ltd	KZA	86.0	Beginning Phase 3

Source: MST, FactSet

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 a 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. However, in MST's view, the premium is unlikely to be recognised in the current investor environment and uncertainty arising from the FDA enquiries.

The valuation approach based on an average of the three Phase 1/2 trials presents a 12-month forward valuation of A$22m versus current market capitalisation of A$6.7m. Market confidence on news of the SAD trial outcome and confirmation of the format and regulatory approval for the trial to commence is expected to bring investor reassurance – noting the market themes are likely to predominate.

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. MST also acknowledges the current sector investment trends as headwinds in realising the valuation over the short term.

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