IND submission starts the clock

- Island Pharmaceuticals' (ILA) has submitted its Investigational New Drug (IND) application to the US FDA to commence its Phase 2a clinical trial. The submission starts a 30 day clock for the FDA to raise any queries regarding the trial's format.
- ISLA-101 is a repurposed drug with extensive data to support its safety profile. In MST's view, the standing and experience of ILA's clinical trial partners, which include the US Army, provide validation of its program and reduce the clinical trial's risk from design and execution perspectives.
- As a challenge trial, the length of the trial is subject to results of each cohort. MST estimates the Phase 2a trial will conclude by end of H2FY23.

ILA strategy brings advantages

- In comparison to the development of 'first in human' drugs, ILA's strategy is to focus on repurposing drugs for viral illnesses. The strategy potentially brings advantages including lower development costs, faster timelines and lower risk.

- The mechanism of action of ISLA-101 supports potential application in a number of viral illnesses. The first target is Dengue Fever. The selection is strategic, leveraging the advantages of its drug repurposing strategy. ISLA-101 also promises potential use in Yellow Fever virus, West Nile virus, Japanese encephalitis and Zika virus.

Valuation, Risks, Sensitivities

MST valuation is based on the average market capitalisation of a cohort of ASX listed biotechs in Phase 2 trials, a similar stage of development. MST accounts for ISLA-101's strong safety profile and lower risk disease target with a 25% probability of approval versus industry average of 15%. It provides a 12 month forward valuation of A$76.6m. MST notes realisation of the valuation over the short term will be difficult but expects positive Phase 2a results in H2CY23 to see a re-rating of the stock. The valuation is subject to usual upside/downside risks of drug development.

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 lead program in dengue infection is planned to start Phase 2a trials in FY23. There are no approved treatments. ILA's drug, repurposed fenretinide, offers application in a number of other viral related illnesses. ILA's agreements with three Australian drug compound research facilities aim to build a strong pipeline of drugs for other indications.

Ticker Code	ILA.AX
Market Capitalisation	A$14.2m
Share Price	A$0.18
Valuation	A$0.63 (unchanged)

Potential Milestones	
H2FY23	1st Subject enrolled in Phase 2a trial
H2FY23	Results Phase 2a
H2FY23	End of Phase 2a FDA meeting

ILA.AX Share Price (A$)

Source: Factset

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Financial Summary

Island Pharmaceuticals Limited — ILA-AX

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.18**
52 week low / high	A$	0.12 - 0.29
Valuation (12 month forward)	**A$**	**0.63**
Market capitalisation	**A$m**	**14.2**
Shares on issue	m	81.3
Options	m	14.4
Other equity	m	25.0
Potential Shares on issue (diluted)	m	120.7

12 month performance

INVESTMENT FUNDAMENTALS		FY21	FY22	FY23E	FY24E
EPS Reported (undiluted)	¢	(11.4)	(3.2)	(4.4)	(4.5)
EPS Underlying (undiluted)	**¢**	**(11.4)**	**(3.2)**	**(4.4)**	**(4.5)**
Underlying EPS growth	%	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**

KEY RATIOS (A$)		FY21	FY22	FY23E	FY24E
Forecast year end shares	m	81	81	81	81
Market cap (Y/E / Spot)	**$m**	**14.2**	**14.2**	**14.2**	**14.2**
Net debt /(cash)	$m	(6.5)	(4.8)	(6.2)	(2.6)
Enterprise value	**$m**	**7.7**	**9.4**	**8.0**	**11.6**
EV/Sales	x	n/a	n/a	n/a	n/a
EV/EBITDA	**x**	**(3.6)**	**(3.6)**	**(2.2)**	**(3.2)**
EV/EBIT	x	(3.6)	(3.6)	(2.2)	(3.2)
Net debt / Enterpprise Value	x	(0.8)	(0.5)	(0.8)	(0.2)
Gearing (net debt / EBITDA)	**x**	**3.0**	**1.8**	**1.7**	**0.7**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	(0.0)
Price to operating cash flow	**x**	**(16.5)**	**(7.6)**	**(4.0)**	**(3.9)**
Free cash flow	**$m**	**(0.9)**	**(1.9)**	**(3.6)**	**(3.6)**
Free cash flow per share	$	(0.01)	(0.02)	(0.04)	(0.04)
Price to free cash flow	**x**	**(16.5)**	**(7.6)**	**(4.0)**	**(3.9)**
Free cash flow yield	**%**	**-6.1%**	**-13.2%**	**-25.1%**	**-25.6%**
Book value / share	$	0.08	0.05	0.07	0.03
Price to book (NAV)	**x**	**2.2**	**3.3**	**2.5**	**6.7**
NTA / share	$	0.08	0.05	0.07	0.03
Price to NTA	**x**	**2.2**	**3.3**	**2.5**	**6.7**
EBITDA margin	%	n/m	n/m	n/m	n/m
ROE (Average Equity)	%	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	n/m	n/m

PROFIT AND LOSS (A$)		FY21	FY22	FY23E	FY24E
Revenue & Other Income	$m	-	-	-	-
Expenses	$m	(2.1)	(2.6)	(3.6)	(3.6)
EBITDA	**$m**	**(2.1)**	**(2.6)**	**(3.6)**	**(3.6)**
D&A	$m	-	-	-	-
EBIT	**$m**	**(2.1)**	**(2.6)**	**(3.6)**	**(3.6)**
Interest	$m	-	-	-	-
Pre-tax Profit	**$m**	**(2.1)**	**(2.6)**	**(3.6)**	**(3.6)**
Tax	$m	-	-	-	-
Underlying NPAT	**$m**	**(2.1)**	**(2.6)**	**(3.6)**	**(3.6)**

BALANCE SHEET (A$)		FY21	FY22	FY23E	FY24E
Cash	$m	6.5	4.8	6.2	2.6
Receivables	$m	0.1	0.0	0.0	0.0
Inventory	$m	-	-	-	-
PPE	$m	-	-	-	-
Other	$m	0.1	0.1	0.1	0.1
Total Assets	**$m**	**6.6**	**4.9**	**6.3**	**2.7**
Creditors	$m	0.2	0.5	0.5	0.5
Borrowings	$m	-	-	-	-
Other	$m	0.0	0.0	0.0	0.0
Total Liabilities	**$m**	**0.2**	**0.6**	**0.6**	**0.6**
Shareholder's equity	**$m**	**6.4**	**4.3**	**5.7**	**2.1**

CASH FLOW (A$)		FY21	FY22	FY23E	FY24E
Receipts from customers	$m	-	-	-	-
Payments to suppliers and employees	$m	(0.9)	(1.9)	(3.6)	(3.6)
R&D rebate	$m	-	-	-	-
Milestones	$m	-	-	-	-
Interest	$m	-	-	-	-
Tax	$m	-	-	-	-
Other	$m	0.1	-	-	-
Operating cash flow	**$m**	**(0.9)**	**(1.9)**	**(3.6)**	**(3.6)**
Capex	$m	-	-	-	-
Acquisitions	$m	-	-	-	-
Other	$m	-	-	-	-
Investing cash flow	**$m**	**-**	**-**	**-**	**-**
Borrowings	$m	0.0	-	-	-
Equity	$m	7.3	-	5.0	-
Dividend	$m	-	-	-	-
Financing cash flow	**$m**	**7.3**	**-**	**5.0**	**-**
Change in Cash / FX	$m	6.4	(1.9)	1.4	(3.6)
Year end cash	**$m**	**6.5**	**4.8**	**6.2**	**2.6**

Source: Company Reports, MST estimates

Investment Thesis

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

Repurposed drugs offer:

1. Lower risk: ILA.AX is seeking approval to commence its Phase 2a trial. At the start of clinical trials, a first-in-human drug faces significant efficacy and safety risks. ILA's fenretinide offers data from 45+ clinical trials that support its safety in cancer and other non-viral diseases. Safety accounts for some 30-45% of clinical trial failures. MST thereby has applied a higher rate of success for the clinical trial program.
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.

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 Zika Virus. ILA's strategy for dengue can be leveraged in 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 until 2034.
4. From a competitive perspective, there are no approved treatments for its first target, Dengue Fever - noting that there are a number of treatment and preventative candidate therapies in development.
5. The wide geographic and populous area endemic to dengue fever offers 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.
6. ILA's approach is further supported by noteworthy partners, US National Cancer Institute (NCI) and the US Army. The ILA Board offers a depth of scientific and commercial expertise.

Potential Milestones

H2FY23

- 1st Subject enrolled in Phase 2a PEACH trial
- Phase 2a trial results
- End of Phase 2a meeting with FDA

Valuation, Risks, Sensitivities

MST valuation is based on the average market capitalisation of a cohort of ASX listed biotechs in Phase 2 trial, a similar stage of development to ISLA-101. MST applies a premium to reflect firstly, ISLA-101's strong safety profile from earlier 45+ clinical trials and secondly, its target of infectious diseases which carry a lower risk. It applies a 25% probability of approval versus industry average of 15%.

The valuation approach presents a 12 month forward valuation of A$76.6m. It assumes positive Phase2a trial data. The trial will include first efficacy data, a key milestone for the repurposed drug. MST notes there is risk that the current market trends may prevail and mute the market response.

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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