Phase 2a trial on track for early CY23

IND submission next step

- Island Pharmaceuticals (ILA) has announced that its ISLA-101 (fenretinide) capsules have passed their critical accelerated stability milestone. ILA is now finalising its Investigational New Drug (IND) application to the FDA to allow the commencement of its Phase 2a trial.

- The submission of the IND will start an 'up to' 30-day review period by the FDA. ISLA-101 is a repurposed drug with extensive data to support its safety profile. The Phase 2a PEACH trial is expected to commence in January 2023, under the assumption that there are no queries from the FDA.

- In MST's view, the standing and experience of ILA's clinical trial partners, including the US Army, provide validation of its program and reduce the clinical trial risk from design and execution perspectives.

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.

- ISLA-101 may have 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. We account for ISLA-101's strong safety profile and lower risk disease target with a 25% probability of approval versus industry average of 15%. A 12 month forward valuation of A$76.6m (previously A$112m) reflects the current risk-averse sector investment trends. 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 Cap	A$13.8m
Share Price	A$0.17
Valuation	A$0.63 (previously A$0.83)

Potential Milestones	
H1FY23	File IND
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

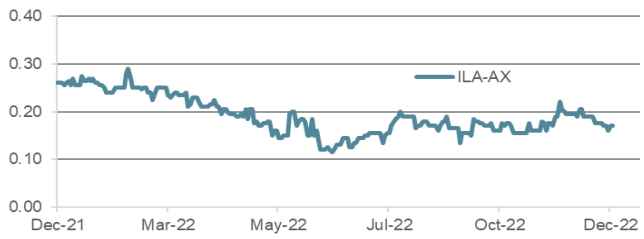
Figure 1 – MST Financial Summary

Island Pharmaceuticals Limited — ILA-AX

Year end 30 June

MARKET DATA		
Share Price	**A$**	**0.17**
52 week low / high	A$	0.12 - 0.29
Valuation (12 month forward)	**A$**	**0.63**
Market capitalisation	**A$m**	**13.8**
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**	**13.8**	**13.8**	**13.8**	**13.8**
Net debt /(cash)	$m	(6.5)	(4.8)	(6.2)	(2.6)
Enterprise value	**$m**	**7.3**	**9.0**	**7.6**	**11.2**
EV/Sales	x	n/a	n/a	n/a	n/a
EV/EBITDA	**x**	**(3.4)**	**(3.5)**	**(2.1)**	**(3.1)**
EV/EBIT	x	(3.4)	(3.5)	(2.1)	(3.1)
Net debt / Enterpprise Value	x	(0.9)	(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**	**(16.0)**	**(7.4)**	**(3.9)**	**(3.8)**
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**	**(16.0)**	**(7.4)**	**(3.9)**	**(3.8)**
Free cash flow yield	**%**	**-6.3%**	**-13.6%**	**-25.8%**	**-26.3%**
Book value / share	$	0.08	0.05	0.07	0.03
Price to book (NAV)	**x**	**2.2**	**3.2**	**2.4**	**6.5**
NTA / share	$	0.08	0.05	0.07	0.03
Price to NTA	**x**	**2.2**	**3.2**	**2.4**	**6.5**
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

IND application last step

IRB approval √, stability testing √ - IND application submission next

ILA has announced that:

1. Institutional Review Board (IRB) approval has been granted for the ISLA-101 Phase 2a PEACH clinical trial. Noting, as is customary, it is subject to ILA's next regulatory step, approval of its Investigational New Drug (IND) application by the US FDA.
2. ISLA-101 drug has passed its 30-day accelerated stability period test. These data signify the last key step before finalising its IND for submission to the FDA to enable ILA to undertake its Phase 2a trial.

ILA plans to submit the IND application imminently. Submission to the FDA triggers a 30-day review period, with a decision expected in late January 2023.

Phase 2a trial design

ILA's **P**rophylactic **E**xamination of an **A**ntiviral in a dengue **Ch**allenge model or PEACH trial is a randomized, double-blind, placebo-controlled trial to assess ISLA-101 in a prophylactic or preventative role in Dengue infection. The trial will entail up to 16 healthy adults aged 18-55 years old who will be infected with an attenuated (weakened) dengue virus. Within each cohort, three participants will receive ISLA-101 while one candidate will be dosed with a placebo drug. Treatment of oral ISLA-101 will be twice daily over 23 days with monitoring including regular blood tests extending to Day 120.

The trials of four cohorts will be undertaken sequentially to examine different dosing levels. The clinical outcomes of each trial will inform the dosing of the next cohort until the most effective dose is determined. Given the design of sequential trials, the duration of the trial program is uncertain. The company estimates the results will be available in July/August 2023.

Novel features expedite ILA's trial program

ILA's clinical program has a number of novel features that offer advantages of reducing time, cost and risk.

Head Start - Straight to Phase 2a

A clinical trial program usually comprises three stages; Phase 1 to investigate the safety and confirm dosing, Phase 2 for ongoing safety monitoring and first signs of efficacy. The larger Phase 3 trial aims to confirm both safety and efficacy. Preclinical studies and some 45 clinical trials of fenretinide in cancer and other diseases bring a wealth of published data. As these earlier trials reported strong safety data in humans, ILA is not required to undertake a Phase 1 clinical trial. It will initiate its program with a Phase 2a trial.

Reuse of Investigational New Drug (IND)

ILA has been granted access to data that were donated to the US National Cancer Institute (NCI) by pharmaceutical company, Johnson and Johnson (J&J) when it ceased its cancer development program of fenretinide. The data provide more insight into the drug and its method of action which has informed the clinical trial program. The data also include a previously approved Investigational New Drug (IND) application. It will form part of ILA's IND application for the Phase 2a trial. The application is a mandatory requirement to allow clinical investigations on unapproved drugs.

US Army Dengue Human infection Model

One of ILA's key partners for the Phase 2a trial is the US Army. It presents with the highest of credentials. In 2015, the US Army Medical Research and Materiel Command (USAMRMC) created its Dengue Human Infection Model (DHIM) in partnership with US State University New York (SUNY) Upstate Medical University. The US Army's experience spans some 45 exposure cycles with volunteers dating back to 1943. Under the Cooperative Research and Development Agreement (CRADA) agreement, ILA has been permitted to access data from a number of previous dengue fever trial subjects. The Phase 1 data from a challenge study conducted by the Walter Reed and SUNY Upstate forms the basis of the control data for the PEACH study. The ability to include the existing data will reduce the total number of subjects for the trial. The data include the USAMMDA's Investigational New Drug (IND) filing with the FDA. Thereby, the agreement offers cost and time savings. As a hospital-based study, in contrast to the more traditional 'field' trials, ILA's clinical program offers less patient risk as the 'active arm' patients will be monitored daily in a clinical setting. The partnership brings a wealth of experience.

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: ILA.AX is preparing for Phase 2a trial. According to the National Institutes of Health (NIH), 80% to 90% of research projects fail before they reach clinical trials. This risk has been obviated for fenretinide. At the clinical stage, a first-in-human drug still faces significant efficacy and safety risks. 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. As of yet, there are no clinical data to indicate its efficacy in viral illnesses. However, preclinical studies present a different mechanism of action in viral illnesses to cancer and early evidence of the drug's efficacy.
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 to 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

H1FY23

- File Investigational New Drug (IND)

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 ISLA-101's strong safety profile from earlier 45+ clinical trials and 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 (previously A$112m), reflecting the current risk-averse market trends on MST's 'comparables'. MST sees the valuation as a 12month forward target supported by positive Phase2a trial data. The trial will include first efficacy data. However, it notes there is risk 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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