Trial to start early CY23

Manufacturing modifications completed, program resumed

- Island Pharmaceuticals (ILA) has announced that its ISLA-101 (fenretinide) capsules have passed the analytical testing stage. On ILA's manufacturer recommendation, some manufacturing modifications were undertaken to improve the performance and stability of the drug. This resulted in some loss of time and additional costs. On completion of the next and final stage, stability testing, ILA plans to file its Investigational New Drug (IND) for approval to commence the clinical trial program.

- The submission of its 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 trial is expected to commence in January 2023, under the assumption 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.

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

- ISLA-101 promises 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 use in Yellow fever virus, West Nile fever virus, Japanese encephalitis and Zika virus.

Valuation, Risks, Sensitivities

MST valuation is based on the average market 'cap' of a cohort of ASX listed biotechs in Phase 2 trial, 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 (industry -15%). It presents a 12 month forward A$112m valuation. It is subject to usual upside/ downside risks and sensitivities of drug development. MST acknowledges the current sector investment trends as headwinds in realising the valuation over the short term.

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	$15.4m
Share Price	$0.19
Valuation	$0.83 (unchanged)

Potential Milestones	
H1FY23	ISLA-101 stability results
H1FY23	Institutional Review Board submission
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

Rosemary Cummins
rosemary.cummins@mstaccess.com.au

Financial Summary

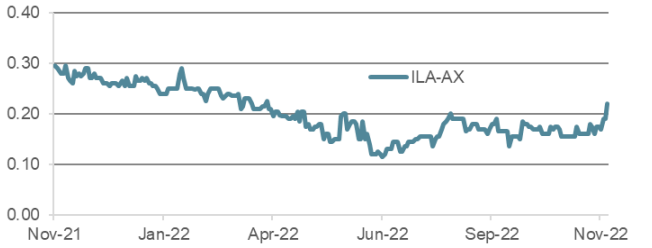
Island Pharmaceuticals Limited — ILA-AX

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.19**
52 week low / high	A$	0.12 - 0.30
Valuation (12 month forward)	**A$**	**0.83**
Market capitalisation	**A$m**	**15.4**
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**	**15.4**	**15.4**	**15.4**	**15.4**
Net debt /(cash)	$m	(6.5)	(4.8)	(6.2)	(2.6)
Enterprise value	**$m**	**8.9**	**10.7**	**9.2**	**12.9**
EV/Sales	x	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
EV/EBITDA	**x**	**(4.2)**	**(4.1)**	**(2.6)**	**(3.5)**
EV/EBIT	x	(4.2)	(4.1)	(2.6)	(3.5)
Net debt / Enterpprise Value	x	(0.7)	(0.4)	(0.7)	(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**	**(17.9)**	**(8.2)**	**(4.3)**	**(4.2)**
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**	**(17.9)**	**(8.2)**	**(4.3)**	**(4.2)**
Free cash flow yield	**%**	**-5.6%**	**-12.2%**	**-23.1%**	**-23.5%**
Book value / share	$	0.08	0.05	0.07	0.03
Price to book (NAV)	**x**	**2.4**	**3.6**	**2.7**	**7.3**
NTA / share	$	0.08	0.05	0.07	0.03
Price to NTA	**x**	**2.4**	**3.6**	**2.7**	**7.3**
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**

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 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 - Noting that there are a number of treatment and preventative candidate therapies in development.
6. 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.
7. 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

- ISLA-101 stability results
- Institutional Review Board submission
- 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 at a similar stage of development. Industry data detailing the risk profiles of different clinical trials have been used to derive a 'risk' weighting for ILA as compared to the average for clinical trials in Phase 2.

We adjust for Isla-101's strong safety profile from earlier 45+ clinical trials and infectious diseases carrying a lower risk. The adjustment sees a 25% probability of approval versus industry average of 15%. It presents a 12 month forward A$112m valuation. It is subject to usual upside/ downside risks and sensitivities of drug development. MST sees the valuation as a 12month forward target supported by positive Phase2a trial data. The trial will include first efficacy data.

The valuation is subject to the upside/downside risks and sensitivities of drug development including 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.

ILA clinical program to start

ISLA-101 quality confirmation

ILA has announced that the ISLA-101 (fenretinide) capsules for its Phase 2a clinical trial in dengue fever have met the required analytical testing criteria. As part of the regulatory process for drug approval the sponsoring company must demonstrate the integrity, quality, and potency of the product over its proposed 'shelf life'. As announced in October 2022, the initial trial capsule batches which were manufactured using more historic methods, had yielded poor physical characteristics. ILA's manufacturer recommended some modifications to improve the performance and stability of the drug, which has resulted in some additional time and cost. The new capsules have shown 'uniformity of content', which is a measure of the consistency of active ingredient in each capsule and have passed their analytical testing. ILA now plans to lodge its submission for ethics approval of the Phase2a trial.

With the quality of the ISLA-101 capsule confirmed, 'stability' or shelf life, the final testing step, will be assessed. The results are expected in early December. On confirmation of stability, ILA will file its Investigational New Drug (IND) application submission with the US FDA in December. The submission will start an up to 30 day review period, with the Phase2a trial expected to commence in 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 will be conducted over FY23. It 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 18-55year old healthy subjects who will be infected with an attenuated (weakened) dengue virus. Up to four cohorts will be included to examine different dosing levels. 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 by regular blood tests extending to Day 120.

As a Phase 2a trial, the primary purpose is to explore the drug in the Dengue Fever setting and inform larger trials designed to demonstrate safety and efficacy to meet regulatory approval. The primary endpoint of the PEACH trial will assess the prophylactic effect of ISLA-101 on fever, clinical symptoms and laboratory markers of viremia. Secondary endpoints will include safety and characterise the clinical, immunologic and virologic responses following ISLA-101 after the dengue challenge. All intellectual property developed through the trial process will belong to ILA.

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.

Re use 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 and can be used to inform 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.

Well credentialled Phase 2 partners bring benefits

i) US Army and SUNY Upstate Medical University

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. The partnership brings a wealth of experience.

ILA has also entered into a Cooperative Research and Development Agreement (CRADA) with the US Army Medical Materiel Development Activity (USAMMDA), a subordinate laboratory of the USAMRMC. USAMMDA is responsible *for the development of new therapies and medical support equipment to 'ensure provision of the highest quality medical care to the Department of Defence (DOD) and maximize survival of medical casualties on the battlefield'*. Many US troops serve in dengue fever infested regions. Under the CRADA, ILA gains access to the attenuated dengue virus and supporting data. SUNY will conduct the trial.

The DHIM sees young, healthy participants deliberately exposed to the dengue virus. The candidates are monitored and assessed to determine the safety and efficacy of the treatment in preventing dengue fever. The trials are conducted within the framework of FDA regulations to minimise risk and ensure well-informed consent. To date, no significant issues have emerged.

Under the CRADA agreement, ILA has been permitted to access data from a number of previous dengue fever trial subjects. Data from trial participants of these earlier trials will form part of the PEACH trial submission for its control arm. 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. The agreement offers cost and time savings. 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 trial endpoints will include fever, viremia, clinical symptoms and other markers.

ii) ICON Government and Public Health Solutions (ICON GPHS)

ILA has also undertaken a Services Agreement with ICON Government and Public Health Solutions (ICON GPHS) Clinical Research Organisation to leverage its DHIM clinical trials expertise. ICON will oversee the conduct of and manage the data from the trial. The company presents high credentials through its association with multiple agencies in the US Government, multinational public health organizations, and global Non-Government Organisations (NGOs). ICON is a preferred Biomedical Advanced Research and Development Authority (BARDA) partner. The group conducted the Pfizer/BioNTech COVID-19 vaccine Phase 3 trial of 44,000 participants.

In summary, ILA management has leveraged the expertise and experience of groups who have in-depth experience in dengue fever. The DHIM brings a highly credentialled partner and offers significant time and cost savings. There are varying commercial arrangements. ILA will meet the US Defence's costs of the dengue virus and testing for the trial. There is no cost for the NCI and CRADA data. Monash University has rights to the standard industry royalty streams from revenues that may eventuate, which MST estimates to be in the low single digits. The agreements with ICON and Camargo are at the usual commercial terms.

ILA's cash position was ~A$4 million as at 30 September 2022. MST's model assumes that the company will raise A$5m over FY23 to fund the completion of the trial.

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Level 13, 14 Martin Place, Sydney, NSW 2000
Main +61 2 8999 9988
www.mstfinancial.com.au