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Extract from Bioshares –

Island Pharmaceuticals Shares Surge on Trial Start and Capital Raise

Companies covered: ATX, BOT, CYC, ILA, IMC, OPT, PAB, SOM

Island Pharmaceuticals (ILA: $0.18) has seen a surge in its share price following the start of its Phase IIa dengue fever study and a $3.5 million capital raise (conducted at $0.07 per share).

The Phase IIa study is a prophylactic assessment of its lead candidate, ISLA-101, against infection by the dengue virus. Four patients have been enrolled in the study; three have received ISLA-101 and one patient a placebo. After three days all four are to have been infected with an attenuated (weakened) version of the virus.

Subjects will be followed for 90 days measuring viral load and other virus infection symptoms. Results are due this quarter. The virus strain being used was initially developed as a vaccine by the US Army but found to cause a mild form of dengue fever. This makes it a suitable substitute in clinical studies rather than using the more deadly form of the virus.

This study is expected to be followed with a therapeutic challenge study in which 10 volunteers will be recruited. Those subjects will be infected with the same attenuated virus. Eight will then be treated with ISLA-101 and two with placebo for seven days after infection. The virus is supplied by the US Army.

One of the benefits of being able to conduct a challenge study with healthy volunteers is that the study numbers can be much lower than if a field study was conducted in patients naturally infected with dengue.

The Phase IIa study is being conducted at Suny Upstate Medical University in New York under Professor Stephen Thomas who is on the company's Medical Advisory board and heads the infectious diseases unit at that university hospital.

Results from these Phase II studies will be shared with the US Army which developed the strain being used and has requested to see the results. Results are due late March or early April next year. The Department of Defense is providing US$652,000 towards these Phase II studies. The DoD is also potentially a major customer for these therapy should it reach the market.

The effects that can be expected from dengue infection from this strain include abdominal pain, eye pain, rash, nausea, vomiting and possibly fever.

Appropriate Dose Selected in Phase I Studies

A previous Phase I study has selected the appropriate dose that is expected to deliver efficacy in the Phase II studies. Monash university has identified the EC_{50} dose (that required to kill half the virus level in the body) as 0.81 µM. Island knows from its Phase I studies that it can achieve drug levels in the bloodstream well above this level (without side effects) said CEO David Foster.

Continued over

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-35.8%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - May '21)	86.8%
Year 21 (May '21 - May '22)	-15.6%
Year 22 (May '22 - Dec '22)	-2.2%
Year 23 (CY2023)	-15.4%
Year 24 (CY2024)	33.5%
Cumulative Gain	1796%
Av. Annual gain (23 yrs)	16.6%

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Preclinical Results

In a mouse study, mice were injected with a deadly strain of the dengue virus. Those that did not receive ISLA-101 were all dead after five days. However 70% of those that received two doses a day of ISLA-101 survived, with that survival effect being dose dependent. In the Phase II studies, the dose used will be about 10 times the equivalent dose used in that mice study for humans.

Background of ISLA-101

ISLA-101 has been assessed in 45 clinical studies for other indications. Its drug profile is well understood. Its mechanism of action against the dengue virus was established by Monash researchers. It works by protecting a host's (person's) nucleus from the virus, not allowing viral replication. (In detail, for the virus to replicate, an NS5 protein from the virus needs to cycle in and out of the host cell nucleus. ISLA-101 inhibits the movement of NS5 into the nucleus.) This is the same mechanism when used prophylactically or as a therapeutic post infection.

In preclinical models conducted at Harvard University and Monash, the drug candidate has been shown to be effective against dengue, West Nile, yellow fever and the Zika virus. In *in vitro* studies with human cells, ISLA-101 has been shown to offer strong anti-viral effects. Foster said that the two research groups (Harvard and Monash) validated each other's work (making the data highly objective).

ISLA-101 was found by researchers at Monash University who were screening compounds for activity against dengue virus (all four strains). ISLA-101 was previously developed by Johnson & Johnson as a potential therapy in oncology but was unsuccessful due to insufficient efficacy. However the company believes the company is a very good anti-viral compound.

Dengue Infection Spreading from the Equator

According to the company, 400 million people are infected with the dengue virus every year making it a very large, unmet clinical need with no therapeutics. CEO David Foster said that some vaccines are approaching the market however they are imperfect with need for improvement remaining. Hot spots for the dengue virus include Vietnam, Barbados, Peru, Malaysia, Singapore, Bangladesh and Sri Lanka with the virus spread now moving away from the equator. Dengue infections have also reached the US, including in California. By 2050, dengue infections are predicted to impact areas further from the equator, including the northern third part of Australia.

Second Drug Candidate - Due Diligence Underway

Island's model is to in-license previously tested drug candidates for new indications that have been through mid-stage clinical testing, potentially bringing products to market in a more rapid path. Other appealing features for new assets the company assesses include open INDs, validated interest with US Government funding and with the potential for receiving a Priority Review Voucher (worth around US$110 million upon product approval).

The second compound the company is assessing is galidesivir, which had been initially developed by BioCryst Pharmaceuticals. Last month Island signed a binding letter-of-intent to in-license the compound, pending the completion of due diligence which is underway. Whether the compound can be brought to market using the 'Animal Rule' pathway may need to be determined from the FDA. If it can, it means that human clinical studies may not be required, considerably shortening the path to market. Galidesivir has shown broad activity against a number of viruses including Ebola, Marburg and Zika viruses.

Both ISLA-101 and galidesivir are eligible to receive the Priority Review Voucher upon approval. Island is also actively looking for other compounds to in-license that align with its rapid path to market and Priority Review Voucher eligibility.

Some of the appeals of this drug candidate (galidesivir) include completed Phase I studies, and completed non-human primate studies with a number of viruses. The safety profile of galidesivir has also been well established.

Summary

Island Pharmaceuticals is capitalised at $28 million. The funds raised recently will provide the company with sufficient cash to complete the current Phase II studies, complete due diligence on galidesivir, and acquire this asset. The company's proforma cash balance at the end of June was $5.2 million (including the recent capital raise).

If Phase II results in dengue are positive the company will meet with the FDA to discuss the Phase III trial protocol and consider funding options to conduct the registration study or seek to out-license the program to a larger partner for upfront payments and future royalties from product sales.

The next study with ISLA-101 would likely not be a challenge study but a field study where the virus is active in the population.

Bioshares recommendation: **Speculative Buy Class B**

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Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages of commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

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