COMBATTING URGENT VIRAL DISEASE THREATS

DR DAVID FOSTER, MANAGING DIRECTOR

Annual General Meeting, 19 November 2024

(ASX: ILA)

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Island Pharmaceuticals (ASX:ILA) is an antiviral therapeutics company targeting infectious diseases

STRATEGY:

- Known small molecules with clinical history
- Mid/late stage clinical or other abbreviated routes
- Open US FDA INDs
- Validated US Govt/military funding support
- Priority Review Voucher eligible

RAPID PATHS TO MARKET

ISLAND PHARMACEUTICALS

Antiviral therapeutics

A YEAR IN REVIEW

ISLAND PHARMACEUTICALS
Antiviral therapeutics

FY24 highlights

Beneficiary of USD 624k in DoD grant funding for PROTECT study

Key US patent granted for ISLA-101

Single Ascending Dose study successfully starts, finishes and reads out

$1.95m fully underwritten rights issue completed

Data modelling introduces time and cost efficiencies for next trial

PROTECT study redesigned to include preventative and therapeutic arms

FY25 to date

Filed Single Ascending Dose study report with US FDA

Next ISLA-101 study renamed PROTECT and expanded to Phase 2a/b

Phase 2a (preventative) arm of ISLA-101 PROTECT study commences

Binding letter of intent executed for second asset, Galidesivir

Dr David Brookes retires from the Board and Chris Ntoumenopoulos joins as NED

Paul MacLeman and Anna Lavelle retire from Board, Phil Lynch joins as Executive Chair

"FY24 was, by all measures, a significant year for your Company. As part of advancing our mission to provide drugs that can address urgent viral diseases and public health or biosecurity threats, we made major strides in the development of our lead drug candidate, ISLA-101 through the period."

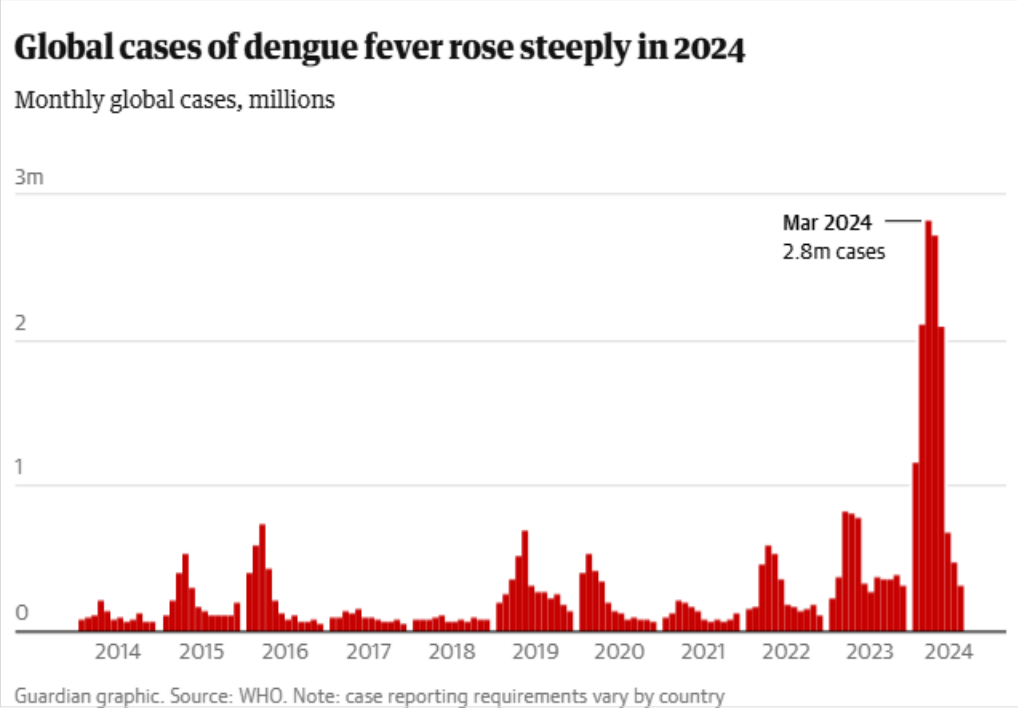
Dr Paul MacLeman and Dr David Foster

$3.5m capital raise supported by existing and new investors

“About half of the world's population is now at risk of dengue with an estimated 100–400 million infections occurring each year”

World Health Organisation, 30 May 2024

DENGUE IS A WIDESPREAD ISSUE



WORLD ECONOMIC FORUM

Join us

CLIMATE ACTION

The world is in the grip of a record dengue fever outbreak. What's causing it and how can it be stopped?

Nov 5, 2024

The Guardian

Aus

Sport | Culture | Lifestyle

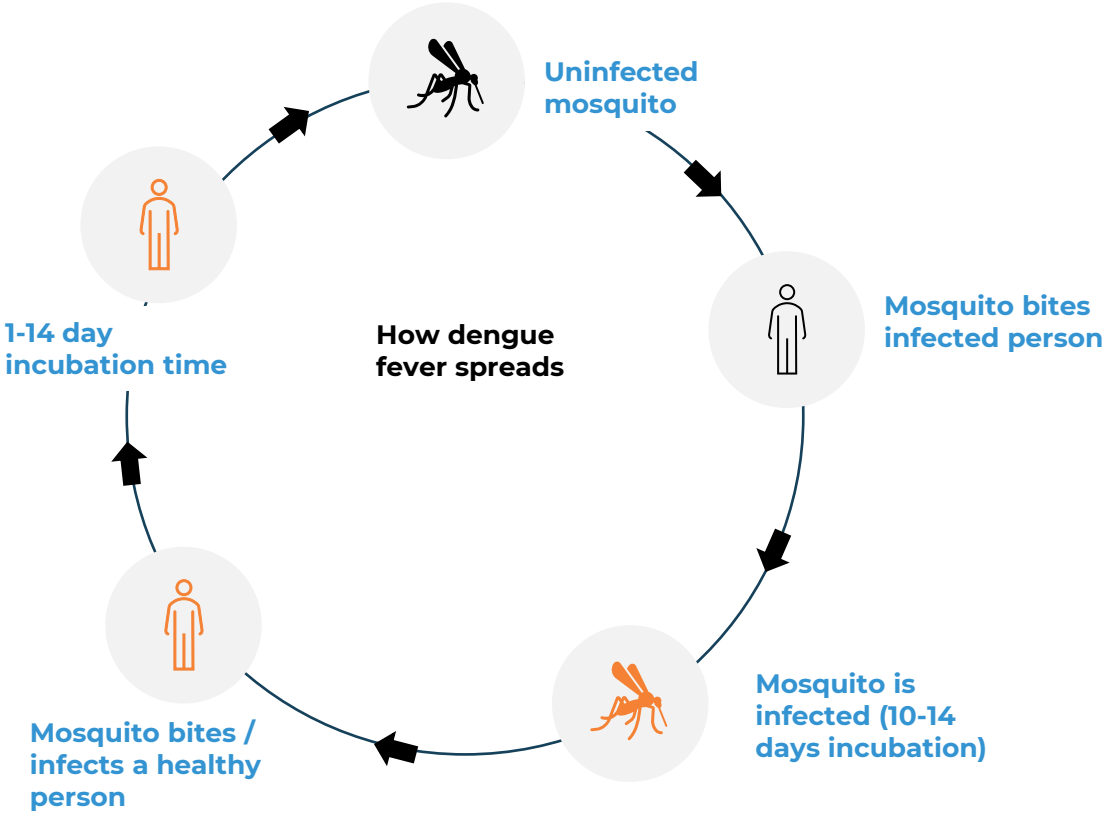
Australia Middle East Africa Inequality Global development

Dengue fever: with a record 12.4m cases in 2024 so far, what is driving the world's largest outbreak?

Cases of 'bonebreak fever' are on the rise, mostly in Latin America, Africa and south-east Asia. But incidences in Europe and the US are also being recorded – with an estimated 4 billion people at risk worldwide

Advertisement

INFECTION AND SPREAD



Why the surge in dengue infections?

Warmer temperatures

- Accelerate development
- Increase activity of female mosquitoes
- Reduce incubation time for mosquito to become infectious
- Allow mosquitoes to survive longer through winter

High humidity

- Improves mosquitoes' chance of survival

Extreme weather

- Disrupts water / sanitation
- Increased flooding can enhance breeding

ENTER, THE TIGER MOSQUITO *(AEDES ALBOPICTUS)*

- A new mosquito, Aedes Albopictus is on the scene
- According to ECDC, the mosquito has been recorded as newly established in regions in France and Germany, and newly introduced into regions in Spain, the Netherlands, Portugal, and Slovenia.
- *The speed at which Aedes Albopictus* has contributed to the dengue problem was completely unexpected
- It is a warning for anyone NOT living in tropical areas that the dengue train is coming down the tracks

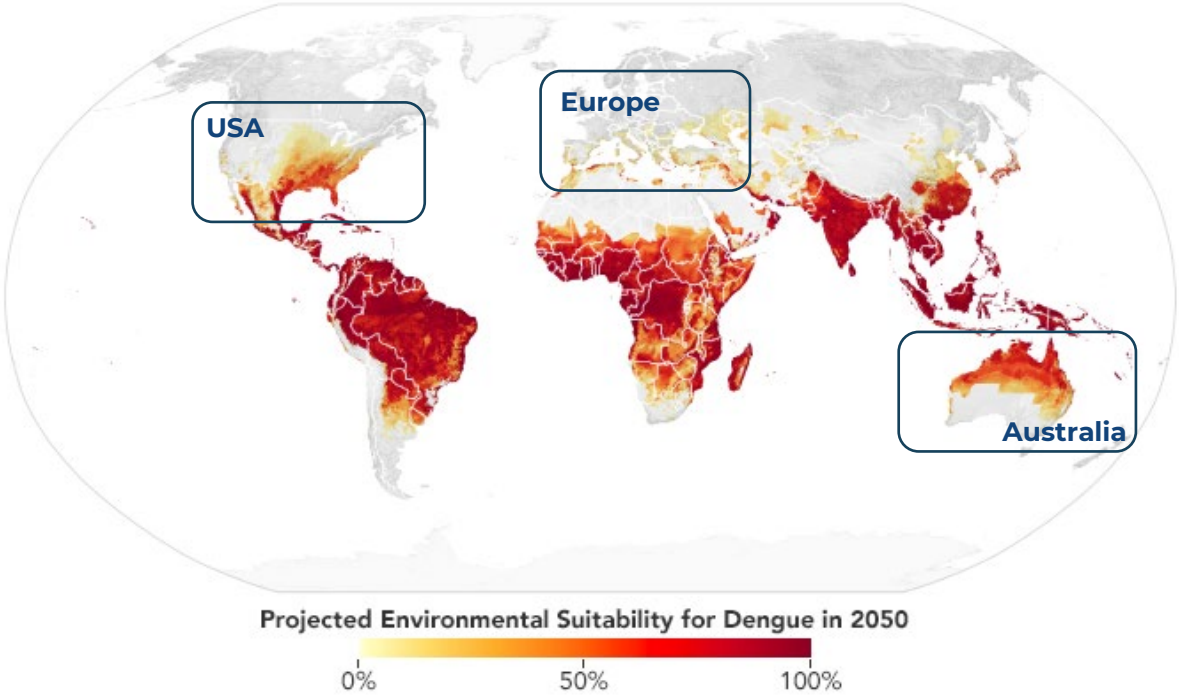
Additional analysis

Figure 74: Percentage change in yearly average dengue estimated $\mathbf{R_0}$ *for Aedes Albopictus and Aedes Aegypti globally in the period 1950–2023.*

https://www.ecdc.europa.eu/en/publications-data/aedes-albopictus-current-known-distribution-may-2024 | Figure 74 source: Supplement to: Romanello M, Walawender M, Hsu S-C, et al. The 2024 report of the Lancet Countdown on health and climate change: facing record-breaking threats from delayed action. *Lancet* 2024; published online Oct 30. https://doi.org/10.1016/ S0140-6736(24)01822-1.

DENGUE IN 2050 – A GLOBAL DISEASE

Prediction based on projections of future temperatures, rainfall, and mosquito populations



NASA Earth Observatory map by Lauren Dauphin based on data from Janey Messina, University of Oxford - https://earthobservatory.nasa.gov/features/disease-vector

About ISLA-101

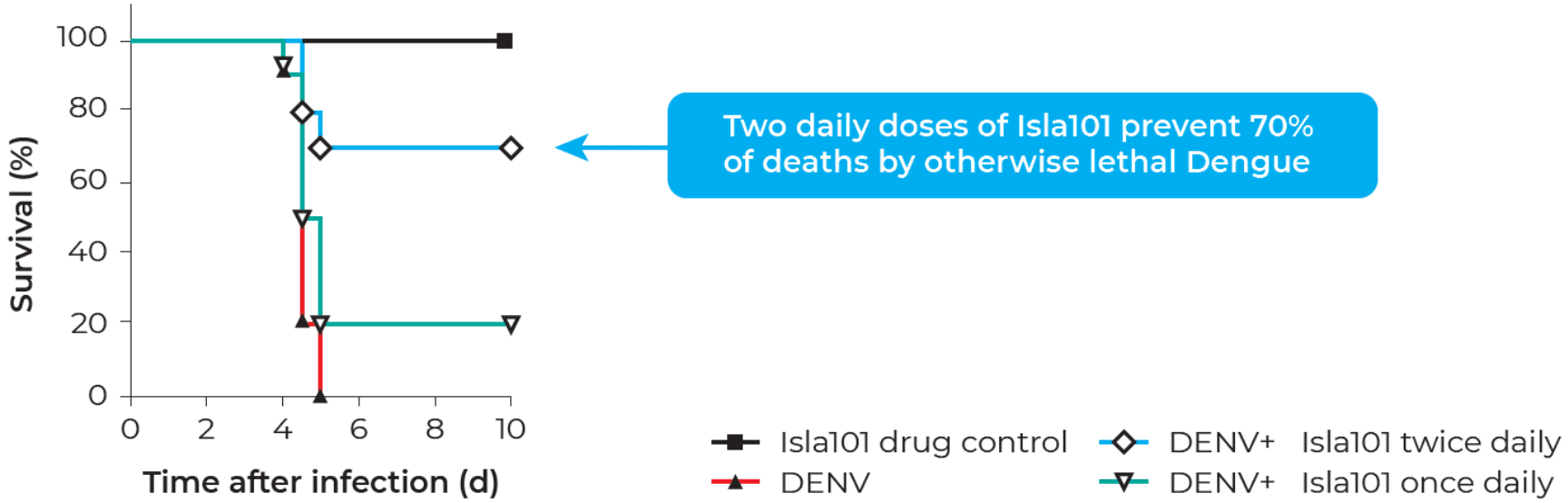
ISLA-101 BROAD ACTIVITY EVIDENT

Demonstrated activity against flaviviruses (a subgroup of arboviruses) in multiple models of infection

- In *in-vitro* models ISLA-101 has demonstrated broad anti-viral activity
- In *in-vitro* models using fresh human cells, ISLA-101 has demonstrated potent anti dengue-1 activity
- In animal models, ISLA-101 is protective in dengue fever and Zika
- In extremely lethal animal models, ISLA-101 was shown to prevent death in 70% of subjects
- Increasing concentrations of ISLA-101 prevent death induced by an otherwise lethal dengue fever infection
- 45 HUMAN Clinical Studies of ISLA-101 completed in other indications
- *Island's own Single Ascending Dose study and further modelling reinforced safety / tolerability and identified Phase 2 dosing*

PREVENTS ANIMAL DEATHS FROM LETHAL DENGUE

ISLA-101 has also been shown to be protective in animal models of both dengue and Zika Virus.



Survival curve showing protection from lethal dengue change by Increasing dose of ISLA101 (mouse model).
Fraser et al. J. Infect. Dis 2014

PHASE 2a/b DENGUE (PROTECT) TRIAL STUDY

"PROTECT" study- A Phase 2a/b, Randomized, Double blind, Placebo-controlled Dengue Challenge Study – a PROphylactic and TrEatment Challenge Trial

The study will be conducted at SUNY Upstate Medical University Syracuse, New York.

Phase 2a/b trial protocol: 2 cohorts

1. Prophylactic Cohort- 2A: 4 subjects randomized 3:1
2. Therapeutic Cohort: 2B: 10 subjects randomized 8:2

Primary endpoint

- Assess the effect of ISLA 101 on clinical signs and symptoms after challenge with DENV-1-LVHC

Secondary endpoints

- Characterize the clinical, immunologic and virologic responses following ISLA 101 after challenge with DENV-1-LVHC
- Assess the safety of ISLA 101 in the challenge with DENV-1-LVHC

US$624k Congressionally Directed Medical Research Programs (CDMRP) grant awarded to The Research Foundation for SUNY to directly support PROTECT study.

PHASE 2a/b CLINICAL TRIAL DESIGN

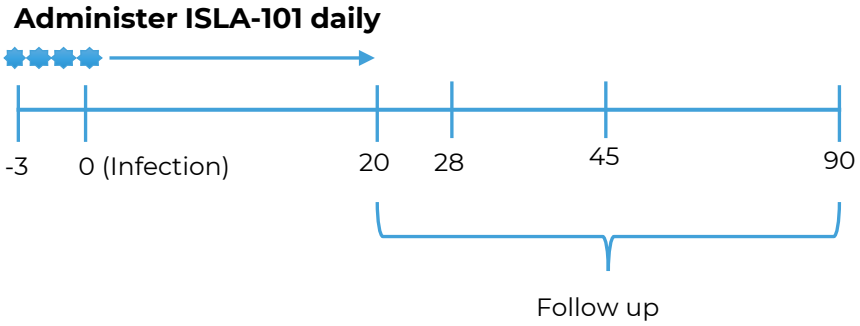
Phase 2a/b trial protocol: 2 cohorts

1. Prophylactic Cohort- 2a (left): 4 subjects randomized 3:1
2. Therapeutic Cohort: 2b (right): 10 subjects randomized 8:2

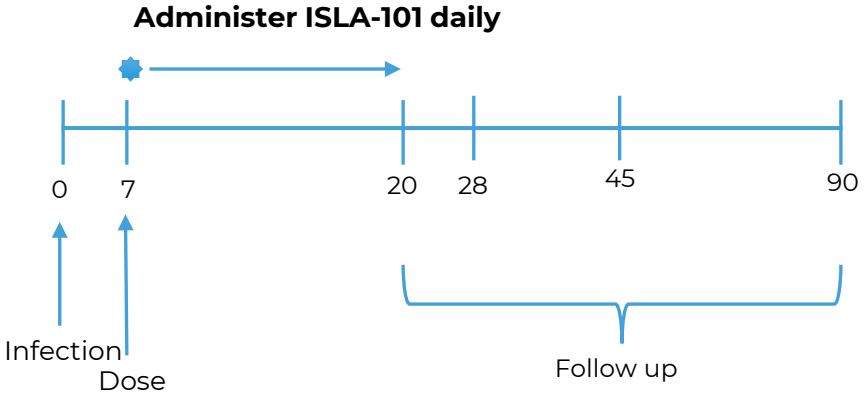
Key near-term milestones:

- Ethics approval received in August 2024, patient screening began in early September, with dosing expected to start imminently
- *Phase 2a read out expected by the end of 2024*
- *Phase 2b cohort dosing expected to commence in Jan 2025*

Phase 2a: Prophylactic (preventative) cohort



Phase 2b: Therapeutic (treatment) cohort



WHY A CHALLENGE STUDY?

"When there are no available animal models of a disease, researchers take a weakened form of the virus and create a mild, safe form of the disease in a healthy person. The idea is that in a safe, well-controlled environment using a small number of people, we can get information that normally would involve going into the field and exposing a lot more people.

It is good timing for Island to test their product ISLA-101, now that it has successfully passed the Phase 1 safety study. The Phase 2 trial then can examine, in a small, very controlled and safe environment, if ISLA-101 has an impact on viral replication in humans, the symptoms, and the immune response."

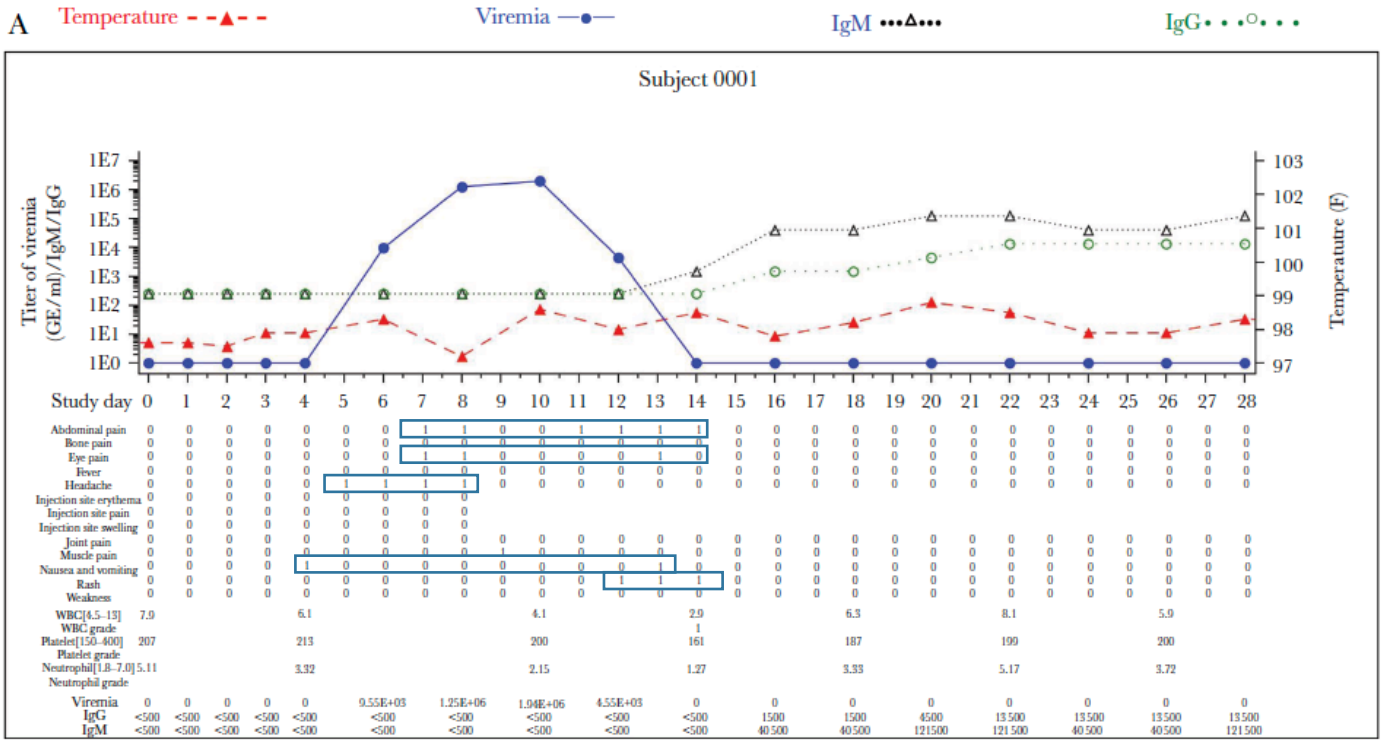
Professor Stephen Thomas MD
Director, Update Global Health Institute

PHASE 1 CONTROL DATA DEMONSTRATES BENEFIT OF CHALLENGE STUDY APPROACH

A Phase 1 challenge study conducted by Walter Reed and SUNY Upstate forms the basis of Island's PROTECT study control data, and enabled unprecedented ability to monitor dengue symptoms, including:

- Abdominal pain
- Eye pain
- Fever
- Headache
- Nausea and vomiting
- Rash

Island will use the same attenuated virus and approach in its coming Phase 2 study.



Endy et al, J Inf Dis 2021


ISLAND
PHARMACEUTICALS
Antiviral therapeutics
PIPELINE BUILD, OPPORTUNITIES AND MILESTONES

STRATEGIC CHECKLIST

- Clinical history
- Small molecule
- Proven preclinical anti-viral activity
- Eligible for Priority Review Vouchers
- National and military preparedness need
- Probable/confirmed non-dilutive funding to support: military, civilian, NGO
- Fit for our management and advisory team: mid/late stage drug development, extensive medical countermeasures experience and roles

TARGETING KNOWN OR RE-PURPOSABLE DRUGS WITH REDUCED TIME TO MARKET

GALIDESIVIR – Ebola, Marburg, Zika & and many other RNA viruses

- 12 month, **binding** Letter of Intent signed 11 September 2024
- Substantial Phase I human safety data
- Proven protective efficacy in a number of lethal animal models
- If proceed to full option agreement, would be seeking to confirm continued access to FDA's **Animal Rule**
- Extensive US government funding to date
- PRV eligible (multiple options)

COMMERCIAL OPPORTUNITIES

BOTH candidates have prophylactic and therapeutic potential

Travellers

Malaria is also a mosquito borne disease and therefore a proxy for other tropical diseases. Market for anti-malarials is expected to reach US$1B[1] by 2026

Military

Relationship with US Army in place (CRADA, ISLA101). Will continue discussions as programmes advance. Proven interest in both assets.

National Outbreaks

Millions of patients in Latin America & Asia offer potential for sales in disease suppression and treatment during outbreaks of dengue, Zika. Increasing rapidly elsewhere.

Government Stockpiles

Potential for countries to establish civilian and military drug stockpiles as happens with influenza.

Priority Review Vouchers

Last ten PRVs sold for an average of US~$110M, with potential for ISLA-101 and galidesivir at the time of first FDA approval

1. *https://www.alliedmarketresearch.com/anti-malarial-drug-market*

CORPORATE SNAPSHOT

Key data

Share price (AUD[1])	$0.175
Market cap[1]	$28m
Shares on issue[1]	155,910,709
Listed Options[2]	30,584,956
Cash at 30 September 2024[3]	$724k
Placement announced 3 October 2024	$3.5m
DoD grant funding to directly support the Phase 2a/b PROTECT clinical study	USD $625k
Substantial holders	
Dr William James Garner	18.24%
Jason Alan Carroll	16.24%
MWP Partners Limited	7.70%
Dr Daniel Tillett	5.26%

Recent ILA trading history

Board of Directors

Dr Paul MacLeman, Executive Chairman[5]
Mr Phillip Lynch, Incoming Executive Chairman[6]
Dr David Foster, CEO and Managing Director
Mr Albert Hansen, Non-Executive Director
Dr Anna Lavelle, Non-Executive Director[5]
Mr Chris Ntoumenopoulos , Non-Executive Director

1.As at 15 November 2024 | 2. ILAO Option terms: Exercise price of $0.06 expire 14 March 2025. | 3. As at 30 September 2024 – does not take into consideration cash burn since 30 September 2024 or cash received from Placement and options exercised | 4. Shares held per Substantial interest notices lodged with ASX | | 5. As announced on 11 November 2024, Paul MacLeman and Anna Lavelle are resigning following the 2024 Annual General Meeting on 19 November 2024 | 6. As announced on 15 November 2024, Mr Phillip Lynch appointed Executive Chairman from 19 November 2024, post AGM | Share price data sourced from asx.com.au

KEY MILESTONES**

H1 FY 2024 (Jul – Dec 2023)

- Key US and Australian patents granted for ISLA-101
- Obtain HREC (i.e. IRB) approval
- Screen, enrol and dose volunteers in Single Ascending Dose study
- Successful progression through Single Ascending Dose study cohorts

H2 FY 2024 (Jan – Jun 2024)

- Dose final Single Ascending Dose study subject
- Single Ascending Dose study read out
- FDA interaction on Phase 2a/b study protocol
- Pipeline expansion efforts
- Complete in silico modelling of multiple dosing regimen

H1 FY 2025 (Jul – Dec 2024)

- Obtain ethics approval for Phase 2 trial
- Screening subjects in Phase 2a/b trial
- **Subjects dosed in Phase 2a trial arm**
- **Secures $3.5M in funding to support key inflection points**
- Data readout from Phase 2a study
- **Ongoing DD on Galidesivir program**
- **Ongoing discussions with potential partners**

H2 FY 2025 (Jan – Jun 2025)

- Subjects dosed in Phase 2b trial arm
- Data readout from Phase 2b study
- End of Phase 2a/b meeting anticipated with FDA
- Plans announced for next steps in clinical programs
- Ongoing discussions with potential partners

** Dates are indicative only, based on best estimates at the time of writing; subject to change.

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