



**An Innovative, Game-changing
Approach to Cancer Therapeutics:
Succeeding Where Others Have Failed**

March 2022

Dr Philip A Marshall
Chief Executive Officer

About Our Company

Purpose and Mission

Oncology Research International Limited (ORIL) was initially founded by a cancer survivor with the aim to investigate and develop new, effective and low-cost, plant-derived therapies for cancer.

Summary

Innovative technology tackling unmet needs in the rapidly growing cancer market

- *Candidate drug (ORIL019) identified and patented – a new immuno-oncology (I-O) drug therapy*
- *Stimulates the body's immune system to fight cancer*
- *Validated by Nobel Prize-winning science (PD-1 inhibitors)*
- *Unique and proven science – a new and different mode of action to other I-O drugs, selectively kills cancer cells*
- *Stimulates and strengthens rather than weakens the immune system*
- *Suitable as a sole treatment, or in combination with other cancer therapies proven to double tumour reductions*
- *Strong IP portfolio, 100% owned by ORIL*
- *Clear pathway forward to commercialization and ROI*
- *Strong well-credentialed, international Advisory Board, management team & advisors*

Addresses Global Impact Goals

An affordable cancer treatment for the world's poorest and most remote communities

The Problem: Cancer - #2 Killer

A Worldwide Problem

Global Cancer Statistics

New Cases per Year (2020)	19.3 million
Cancer Related Death (2020)	9.9 million
New Cases per Year (by 2040)	28.4 million
Global USD Spending 2021	167 billion
Global USD Spending 2022 Forecast	206 billion

>64%

Projected global increase in the # of cancer cases over the next 10 years



Our Science

What is Immuno-therapy?

- ❑ **Cancer immuno-therapy** is the stimulation of the immune system to treat cancer, improving on the immune system's natural ability to fight the disease, by inducing, enhancing, or suppressing an immune response.
- ❑ **An I-O drug** stimulates the body's own defence systems into action against the invading cancer.
- ❑ **Immuno-therapy** has revolutionized cancer treatment and fundamentally changed the way we view how cancer can be managed.

ORIL has discovered a different, scientifically-validated approach to cancer immuno-therapy and is a first-in-class therapy; ORIL fills the gaps in I-O for combination therapy.

Current Immuno-Oncology Landscape

Spectacular Results to Date But a Few Challenges Remain

- ✓ **Results are spectacular with I-O** when used against the protein PD-1 in several types of cancer eg. lung, renal, lymphoma and melanoma

But.....

- ✗ **Still fails in 80% of patients**
- ✗ **Only results in modest increases in the overall survival rate** (1.6 months)
- ✗ **Treatment is at very high costs** to the patient (US\$120,000+ annually)
- ✗ **Only works in a small subset of cancer types**
- ✗ **No reliable biomarker** yet to predict who responds well and who doesn't
- ✗ Overcoming **tumour resistance and toxicity** remains a problem

ORIL Differs from Mainstream I-O Therapies by Effectively Targeting Today's I-O Challenges

ORIL's Science Validation

Immuno-therapy & Immuno-oncology

2018 Nobel Prize in Physiology or Medicine

- awarded to Dr Tasuku Honjo (Japan) and Dr James P Allison (USA) for their ***“discovery of cancer therapy by inhibition of negative immune regulation”***.

<https://www.nobelprize.org/prizes/medicine/2018/summary/>

The ground-breaking work of Dr. Allison and Dr. Honjo showed how different strategies for inhibiting the brakes on the immune system (such as PD-1 inhibitors) can be used in the treatment of cancer patients.

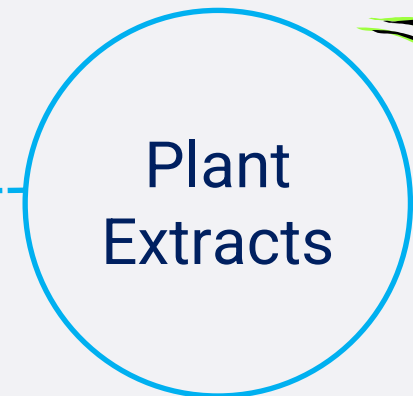
This supports ORIL's strategy.

ORIL R&D and Breakthroughs

The Development Story: Technical Challenges Solved

Starting Point:

Plant extracts with proven **anti-cancer** activity as found in **Traditional Chinese Medicine**



Next: To Clinic/Patients →



Discovery 1:

A new method of manufacture (GMP)
Target and mode of action validated

Discovery 2: Multi-pronged Delivery

New formulations for drug delivery:

- Dermal gel
- Tablets / Capsules
- I.V.

Discovery 3:

A New Generation of Modern Medicine, Re-engineering to Overcome Issues

Design & development of:-

- novel, water-soluble molecules
- safe and well-tolerated by the body
- high efficacy in immuno-therapy

Current Status: there are no more technical barriers to completing pre-clinical trials in the next 18 months.

The Solution

Targets the I-O Challenges

ORIL019 is the Lead Candidate Drug

An extra, potent drug with a different target and mode of action that does not dampen the immune system; acknowledged and recognized science appraised by independent experts during due diligence.

A new family of innovative small-molecule therapies to treat multiple cancers

ORIL Technology

Key Intellectual Property Rights

IP is 100% owned by ORIL

→ facilitates *exclusivity*

New patents further strengthen the *robust commercial exclusivity* put in place through a combination of *composition of matter patents*, method patents and orphan drug exclusivity

Title (Family)	Patent Application Number	Status
Methods and Compositions for promoting activity of anti-cancer therapies	PCT/AU2007/001091	Granted in USA, Canada, China, Europe, India, Australia, Eurasia, Mexico and Japan.
Improved synthesis of a class of steroid saponins (Methods)	PCT/AU2013/000416	Granted in Australia, China, Europe, Mexico Pending in USA and Canada.
Compounds (New Chemical Entities) Composition of Matter	PCT/AU2018/050099	Granted in USA, Australia <ul style="list-style-type: none">• PCT published August 2018• National Phase Entry Aug 2019• Pending Europe, China

ORIL Pipeline Assets Development Platform

Potential in ORIL's Scientific Evidence

Drug Development Pipeline



Under Development

Therapeutic Area	Candidate	Indication	Progress
Oncology	ORIL019	Colon cancer	Progressing through Discovery to Phase I/IB
Oncology	ORIL019	Prostate cancer	Progressing through Discovery to Phase I/IB
Oncology	ORIL019	Pancreatic cancer	Progressing through Discovery to Phase I/IB
Oncology	ORIL019 Combo	Colon, kidney, liver cancer	Progressing through Discovery to Phase I/IB

Discovery Stage

Therapeutic Area	Candidate	Indication	Progress
Anti-inflammatory	ORIL00F	Angiogenesis	Progressing through Discovery
Anti-viral (CoVid-19)	ORIL00F, NCEs	Covid-19	Progressing through Discovery
Anti-TREM2	ORIL00F	Alzheimer's	Progressing through Discovery

Pipeline based on ORIL's view of future designs in clinical trials, according to ORIL019 efficacy data and potential treatment of various indications

ORIL Technology

Other Therapeutic Applications

ORIL recognizes the need to diversify and build its product pipeline based on its platform technology

- **Pathogenic organisms and viruses** e.g., anti-viral application to prevent the virus from “docking” on the host cell thereby preventing invasion and modifying cell processes, including **CoVid-19**
- **Cardiac disease** – #1 global disease killer
- **Inflammatory diseases** – such as inflammatory bowel disease
- **Diabetes** –
 - In 2019, the global prevalence of diabetes was estimated to be 463 million, expected to rise to 700 million by 2045
 - In China alone, it is estimated there are 116 million people with diabetes
- **Neuro-degenerative diseases** such as Alzheimer’s disease
- **Asthma**
- **Cirrhosis of the liver**



Fundraising Plan

Currently at Stage 1 of 3 Tranches of Funding

Stage 1 AUD\$5m (~US\$3.5m) Use of Proceeds

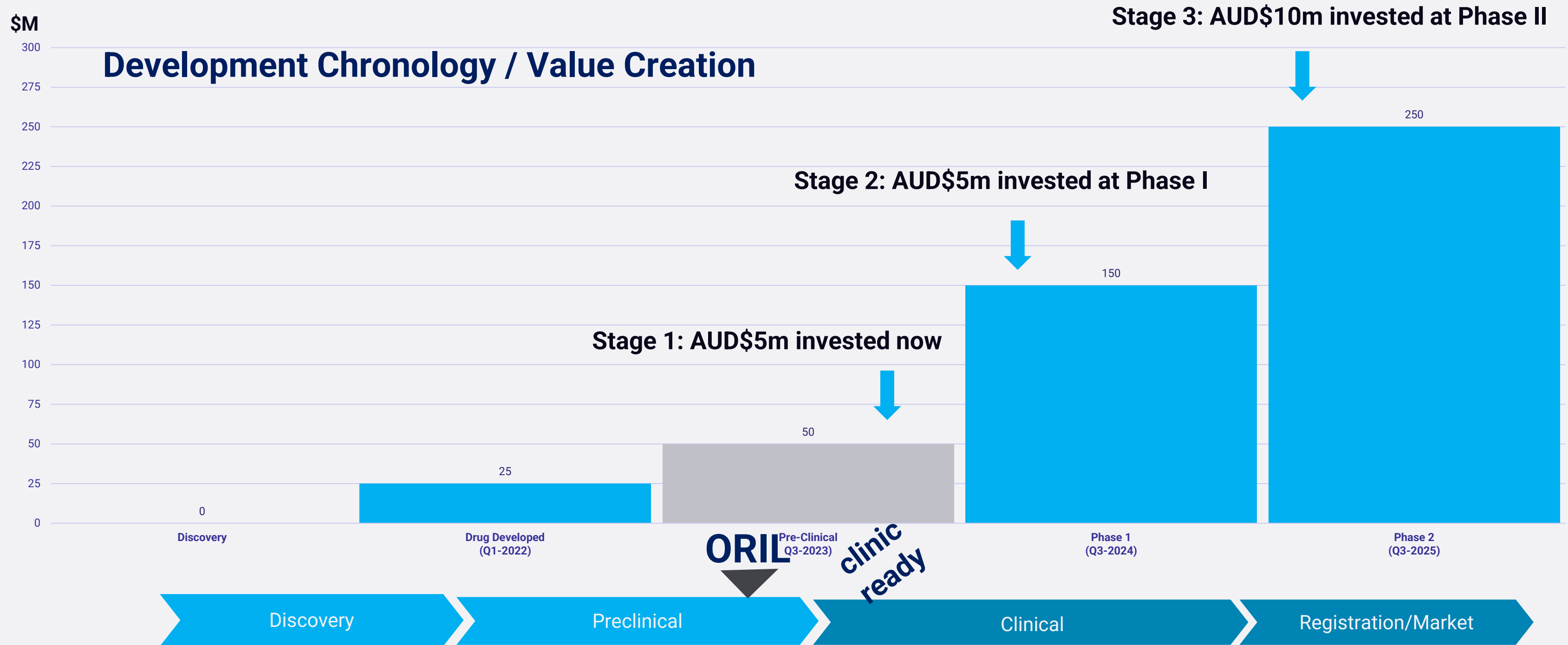
- Seek an immediate capital investment of **AU\$5.0m** to complete pre-clinical in **18 months**
- Phase I/IB studies require further **AU\$5.0m** and **12 months** to complete
- Phase II studies require a further **AU\$10.0m** and is expected to take **~18 months** to complete

Item	Budget (AU\$m)	US\$m
Preclinical R&D (ORIL019) <ul style="list-style-type: none">• Synthesis and scale-up ORIL019• Formulation/product development (i.v./oral)• <i>In vivo</i> efficacy in another model• Bioanalytical development• Dose ranging and optimisation• ADME, PK/PD• Toxicology• Clinic-ready activities	4.3	3.1
Administration Operations, administration, governance, IP and patent portfolio management, support activities, commercial activities, etc.	0.7	0.5
TOTAL	5.0	3.6

R&D expenditure attracts 43.5% tax offset from Australian Tax Office, increasing the value of the R&D \$\$ spent

Fundraising Strategy

Phased Value Formation



Drug development has clear value creation providing exit opportunities with high ROI:
Phase 1 Exit of ~250-280% investor ROI; Phase 2 Exit of ~450% investor ROI.

ORIL's Market Opportunity

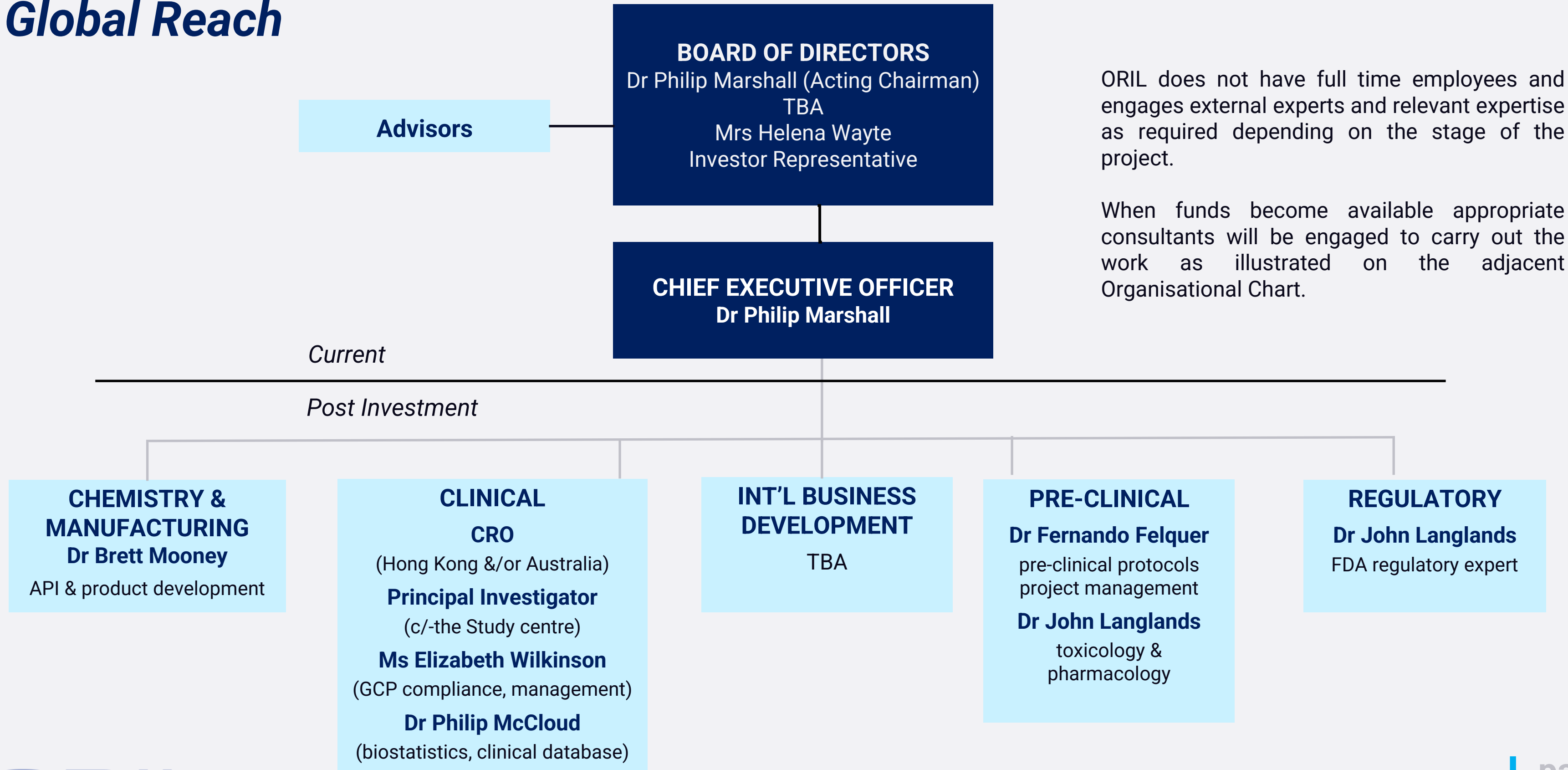
Vibrant Deal Landscape

- **Global Cancer market size** approx. US\$167b in 2021 → [US\\$206b by 2022](#)
- **Immuno-therapy a major driver** behind deal making: [32 of 35 multi-billion deals](#) in last 5 years I-O focused
- **Oncology deal making** shows a steep rise in activity: [combined upfront value of deals 1H2018 of US\\$4.15b](#)
- **58% of deals signed at the discovery stage:** median [upfront payment of US\\$17m](#) in last 5 years
- Early access to innovation important: [60% of deals done at pre-clinical or clinical Phase I stage](#)
- **Small molecules attract a vast majority** of oncology deals: [ORIL019 is a small molecule](#), late pre-clinical stage

ORIL's ROI and exit strategy is designed to reduce risk and offer a range of flexible exit options such as licensing, trade sale, IPO or in-kind collaboration and development; and a high investor ROI is achieved at each exit stage, supported by reduced risks & enhanced certainty.

ORIL Company Structure

Global Reach



ORIL does not have full time employees and engages external experts and relevant expertise as required depending on the stage of the project.

When funds become available appropriate consultants will be engaged to carry out the work as illustrated on the adjacent Organisational Chart.

Company Management

Broad Base of Competence

Key Directors* and Scientific Advisors



Dr Philip A Marshall | Chief Executive Officer | Director & Acting Chairman*

Over 40 years' experience in all aspects of drug design and development. Recognized international expert in pharmaceuticals and in the manufacture of medicines. Held senior executive roles in big and medium Pharma. Founder and Director of global specialist consultancy firm to pharma & biotech. Authorized Aust Govt. GMP Auditor. Co-inventor of the key technology of novel compounds



Professor Wen G Jiang | Medicine and China Relations Advisor

Director of Cardiff China Medical Research Collaborative , UK Director of Cardiff University-Peking University Cancer Institute Honorary professorship at Peking University, Capital Medical University and Inner Mongolia Medical University, Consultant of Beijing Lung Cancer Centre. Created Scholarship in UK devoted to UK-China collaboration in medicine.



Dr Fernando Felquer | R&D Strategy & Project Management

Over 17 years of experience in drug development and biotech. Former VP, Business Development of international CRO vivoPharm. Founder and Director of the advisory firm Innovate Industry Services.



Professor Giuseppe Giaccone | Special Scientific Advisor

Internationally recognized expert in the field of lung cancer and developmental therapeutics. Chief of Thoracic Oncology and Associate Director for Clinical Research at the Sandra and Edward Meyer Cancer Center, Weill Cornell Medicine and New York-Presbyterian Hospital

- ❖ Founding Chairman Prof Gordon McVie, pre-eminent and globally recognised cancer researcher sadly passed away in January 2021. Dr Marshall has assumed the Chair's role until Stage I capital raise has been completed and a new independent chair can be appointed.
- ❖ Founder Dr Michael Wayte sadly passed away on February 19, 2022.

Partners & Collaborators

Entity Name	Location	Website
Charnwood Molecular	Loughborough, UK	https://charnwood-molecular.com/
Diamantina Institute, University of Queensland	Brisbane, QLD, Australia	https://di.uq.edu.au/
GlycoSyn	Lower Hutt, New Zealand	https://www.glycosyn.com/
Keystone Nano	Hershey, Pennsylvania, USA	https://www.keystonenano.com/
Microbial Screening Technologies	Smithfield, NSW, Australia	https://www.microbialscreening.com/
Peter MacCallum Cancer Institute	Melbourne, VIC, Australia	https://www.petermac.org/
QIMR Berghofer Medical Research Institute	Brisbane, QLD, Australia	https://www.qimrberghofer.edu.au/
Quotient Bioresearch	Cardiff, UK	https://www.contractpharma.com/csd/profile/quotient-bioresearch-ltd-
Southern Cross University, Centre for Photochemistry & Pharmacology	Lismore, NSW, Australia	https://www.scu.edu.au/southern-cross-plant-science/
TetraQ	Brisbane, QLD, Australia	https://www.tetraq.com.au/
Translational Research Institute, University of Queensland	Brisbane, QLD, Australia	https://www.tri.edu.au/translational-research-institute-australia
vivoPharm	(Formerly Adelaide SA), Hershey, Pennsylvania, USA	http://vivopharm.com.au/

Contact Details

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