# **ASX Announcement**



19 March 2025

# **INOVIQ INVESTOR WEBINAR PRESENTATION**

**Melbourne, Australia, 19 March 2025:** INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**) advises that CEO Dr Leearne Hinch will be presenting in the ShareCafe Small Cap "Sip and Learn" Webinar on the 19 March 2025.

The details and link to register for the webinar are provided below:

Date: Wednesday, 19 March 2025

Time: 11:00 AM AEDT

Registration: <u>click the webinar link here</u>

A recorded copy of the webinar will be made available following the event on INOVIQ's website. The related presentation slides are attached.

Authorised by the Company Secretary, Mark Edwards.

#### **FURTHER INFORMATION**

**Dr Leearne Hinch**Chief Executive Officer
Chairman

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### **ABOUT INOVIQ LTD**

INOVIQ Ltd (ASX:IIQ) is a biotechnology company pioneering next-generation diagnostics and therapeutics for cancer. INOVIQ has commercialised its fast, efficient and scalable EXO-NET exosome isolation technology for biomarker discovery and diagnostics development, and the hTERT test as an adjunct test for bladder cancer. The company is advancing clinical-stage diagnostics for detection and monitoring of ovarian and breast cancers, and early-stage exosome therapeutics for solid tumours. For more information on INOVIQ, visit <a href="https://www.inoviq.com">www.inoviq.com</a>.





# **INOVIQ** overview

Next-generation cancer diagnostics and therapeutics



Hidden Gems Webinar 19<sup>th</sup> March 2025



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You should note that any past performance is given for illustrative purposes only and should not be relied on as (and is not) an indication of the Company's views on its future financial performance or condition. Past performance, including past share price performance, of INOVIQ cannot be relied on as an indicator of (and provides no guidance as to) future performance including future share price performance.



# INOVIQ Overview | Next generation diagnostics and therapeutics





Exosome powered

Next-gen exosome solutions for earlier detection and treatment of cancer



Disruptive technology

Patented exosome and glycovariant technologies



Products in market

Exosome research tools and bladder cancer test generating revenues



Deep pipeline

Research tools, diagnostics and therapeutics for cancer



Excellent clinical data

Published and in-house data supporting products and pipeline



Partnering for growth

Commercialization via partnering with distributors, clinical laboratories and pharma

- Biotech pioneering next-generation cancer diagnostics and therapeutics to enhance patient outcomes
- Expertise in exosome science, diagnostics, drug development & commercialization
- Leader in high-growth exosome market that is expected to reach US \$6.8 billion by 2032
- Product portfolio includes:
  - ✓ 2 in-market products for exosome research and bladder cancer detection
  - √ 3 in-development glycovariant and exosome diagnostics for detection and monitoring of breast and ovarian cancers
  - early-stage CAR-exosome therapeutic program for solid tumours



# Vision | Leading exosome diagnostics and therapeutics company



## **Strategic Focus**

Next-generation exosome diagnostics and therapeutics for cancer

## **Core Technologies**



#### **Exosome Platform**

NETs™ immunoaffinity, magnetic bead-based EV isolation

EXO-ACE™ affinity chromatography large-scale EV isolation



## **SubB2M Technology**

Proprietary neu5Gc probe for improved cancer detection



### **Research Tools**

EXO-NET® exosome isolation tools for biomarker discovery and diagnostics

Promega



# Diagnostics

**Pipeline** 

Exosome tests for screening, liquid biopsies & companion diagnostics SubB2M tests for cancer monitoring



## **Therapeutics**

Exosome therapeutics to target and kill solid tumours



# Products & pipeline | Multi-stage diagnostics and therapeutics portfolio

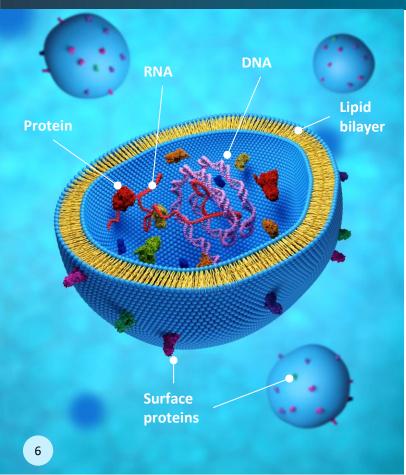


	Product	Indication and Use	<b>Development Stage</b>	Next Milestones (CY)	Market Opportunity
	EXO-NET	Biomarker Discovery & Diagnostics Pan EV Capture	In-Market RUO Promeg	Sales Growth & Collaborations	
Research Too	Is NEURO-NET	Neurology Diagnostics Brain-Derived EV Capture	Commercial RUO	Collaborations	US\$661m
	TEXO-NET	Oncology Diagnostics Tumour-Derived EV Capture	Verification RUO	Validation Data 1H25	
	hTERT ICC1	<b>Bladder Cancer</b> Adjunct to Cytology	In-Market IVD-Class 1 USA		<us\$20m< th=""></us\$20m<>
Diagnostics	neuCA15-3	Breast Cancer Monitoring	Clinical Validation LDT	In-clinic Monitoring data 2H25	US\$4.3b
Diagnostics	neuCA125	Ovarian Cancer Monitoring	Assay Development LDT	Clinical Validation 2026	
	EXO-OC <sup>2</sup>	Ovarian Cancer Screening	Assay Development IVD	Commence Clinical Validation   2Q25	US\$1.7b
Therapeutic	S EEV-001	Breast Cancer CAR-Exosome Therapy	Discovery	In vivo data 2H25	US\$55.3b

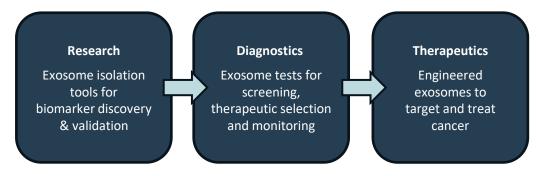


# Exosomes | Significant diagnostic and therapeutic potential





- **Exosomes** are small vesicles released by cells that perform key roles in intercellular communication, immune regulation and disease progression
  - Exosomes carry molecular cargo (DNA, RNA, proteins and lipids) that act as cell messengers or biomarkers of disease
  - > Exosome biomarkers can be used to develop advanced diagnostics
  - Exosomes can be loaded with drugs (small molecules, RNA, other) and engineered for targeted delivery of therapeutics
- Significant investment by large pharma and diagnostic companies in exosome products for Oncology, Neurodegenerative, Infectious & Inflammatory diseases
- INOVIQ's next-gen exosome platform enables multiple applications





# EXO-NET® | Pan-exosome isolation product in-market and generating revenue



Best-in-class **EXO-NET pan-exosome capture** tool (research use only) in-market and generating revenue

Enables **biomarker discovery and diagnostic development** for screening, liquid biopsies and companion diagnostics

Offers speed, efficiency and scalability advantages with over 500 samples/day<sup>1</sup>

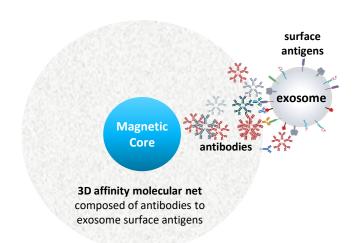
**Data published validating EXO-NET** utility in cancer, neurodegenerative, periodontitis, placental and inflammatory diseases<sup>2,3,4</sup>

**Distribution partnership** with Promega Corporation to market and sell EXO-NET to Academic, Biotech/Pharma & Clinical Lab/Hospital customers worldwide

"[INOVIQ's] new HT exosome isolation and biomarker analysis solution **solves an** industry challenge needed to commercialise exosome-based diagnostics."

Tom Livelli, Vice President, Promega











## NEURO-NET™ | Brain-derived exosome isolation validated & available



Custom **NEURO-NET exosome capture** tool for isolation of brain-derived exosomes

Designed using **proprietary antibody combination** that isolates exosomes secreted from brain cells (neurons, microglia, oligodendrocytes & astrocytes)

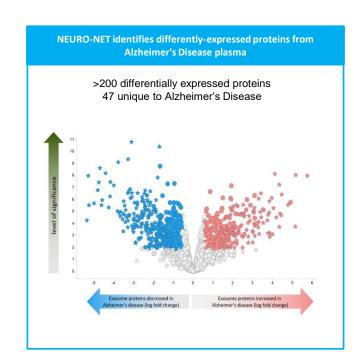
**Exosomes cross the "blood-brain barrier"** and provide a "fingerprint" of the health or disease status of the brain for brain cancer, neuropsychiatric disorders and neurodegenerative diseases

# NEURO-NET analytical and clinical validation studies in Alzheimer's Disease (AD)<sup>1</sup> and Parkinson's Disease (PD)<sup>2</sup> show:

- ✓ NEURO-NET isolates and enriches exosomes from blood that contain proteins expressed by brain cells
- ✓ NEURO-NET was superior to other methods tested for isolating brain-derived exosomes from blood
- Identified known AD & PD biomarkers not detected by other exosome isolation methods
- ✓ Identified >200 proteins differentially expressed between AD & healthy patients
- Validated 47 protein biomarkers providing robust discrimination between AD & healthy

NEURO-NET enables development of exosome diagnostics for neurological conditions.

Brain-derived exosomes hold enormous potential for diagnosis and treatment of neurological diseases.





## **EXO-NET Distribution | Promega Corporation**



- EXO-NET customers: as at 13<sup>th</sup> Feb-25
  - **51 total customers:** won in 6.5 months since Aug-24 (> 8/mo) from EU, US and Asia
  - Applications: Oncology, Neurology, Cardiac Disease, Transplant Rejection, Sepsis & fundamental EV research

#### Product Development:

- Applications development: Joint research ongoing to provide validated data to support customers (urine-based workflows, flow cytometry of isolated EVs, and miRNA/mRNA sequencing)
- Combination products: Developing EXO-NET/RNA combination products that integrate with Maxwell systems and consumables to provide flexible, scalable solutions for EV isolation & diagnostics

### Outlook /Future Steps:

- Multiple evaluations of EXO-NET and NEURO-NET for biomarker discovery and diagnostic development
- Successful evaluations are expected to drive sales of EXO-NET in exosome diagnostic projects over the next 12-months and underpin revenue growth

Customer type	Profile	#
Academic/ Government	Exosome KOLs validating EXO-NET across expanded applications & delivering <i>publications &amp; presentations</i> . Small-vol biomarker discovery & validation data.	21
Pharma/ Biotech/CRO	Focus on <i>patient selection &amp; monitoring MRD</i> . Mid-vol biomarker discovery, companion diagnostics & target identification.	14
Clinical/ Hospital	Key customers requiring a <i>scalable EV isolation solution</i> . Higher-vol sales as projects progress thru development to registration to market.	16
TOTAL		51

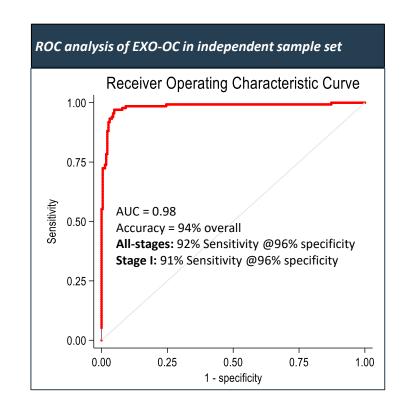


# Exosome Diagnostics | Academic collaboration validating EXO-NET



# Collaboration with UQ to develop blood-based exosomal screening test for ovarian cancer<sup>1</sup>

- UQ¹ OCRF-7 test developed in a 465-sample retrospective case-control study achieving over 90% accuracy for detection of stage I / II ovarian cancer in the discovery set²
- Exosome isolation initially performed using SEC (not compatible with pathology lab workflow) and successfully transferred to INOVIQ's HT EXO-NET exosome isolation technology<sup>3</sup>
- Biomarker validation study completed using EXO-NET exosome isolation in 530-sample independent set achieving overall accuracy of 94% for detection of OC<sup>4</sup>
- Meets critical need for early detection of ovarian cancer to improve treatment options, women's health outcomes and help save lives
- INOVIQ has the exclusive option to license the development and commercialisation rights worldwide<sup>5</sup>







# Ovarian Cancer screening test | Path-to-market



#### **Ovarian Cancer**

- #8 cancer in women & deadliest gynaecological cancer
- 314k new cases of ovarian cancer worldwide pa1
- 0.25% of population has Hereditary Breast and Ovarian Cancer syndrome<sup>2</sup>

# Unmet Medical Need

- No approved test for early detection of ovarian cancer in asymptomatic, averagerisk women
- Earlier and more accurate tests required for screening ovarian cancer

#### **Market Potential**

- US\$1.7b global ovarian cancer diagnostics market<sup>2</sup>
- US\$323m TAM for OC high-risk screening twice yearly<sup>3</sup>

**Test & Data** 

• Exosome multi-marker test validated in a 530-sample retrospective case-control study with overall 94% accuracy and 92% sensitivity at 96% specificity for detection of OC across all stages & 91% sensitivity at 96% specificity for stage 1 alone<sup>4</sup>

Intended Use

• Screening to detect ovarian cancer in asymptomatic high-risk women

## Go-to-Market Strategy

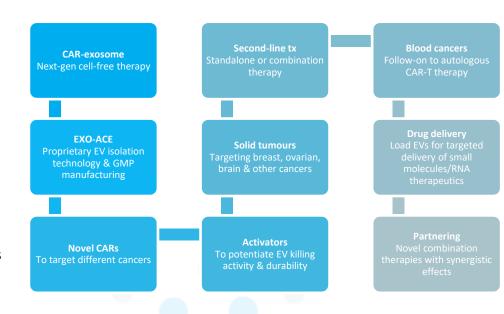
- IVD-MIA regulatory strategy (PMA process) with US FDA
- License to large diagnostics / laboratory company

## Development Path Feasibility Completed Assay Ongoing development Plasma-serum Completed equivalence Biomarker Completed validation study Analytical & Commence 1H25 Clinical validation **IDE** application 2026 Approval 2028

# Exosome Therapeutics | Next-gen cell-free therapy



- INOVIQ is developing weaponised exosomes engineered to target and kill solid tumours
- Next-gen "off-the shelf" cell-free therapy for solid tumours
- The therapeutic effects of Cell Therapy are mediated by exosomes interacting with host cells
- Cell-Free Therapies can be developed using exosomes isolated from allogenic MSC, T cells or NK cells grown in vitro
- CAR-exosomes inherit the targeting and cytotoxic properties of their parent cells to target and kill cancer
- Potential safety, efficacy and cost advantages over autologous CAR-T therapy



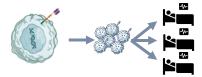


# CAR-Exosomes | Allogenic EV-based therapy with multiple advantages



Engineer Establish Master Cell Expand Isolate EVs In vitro efficacy In vivo animal studies IND Phase I/II Clinical Trials

- ✓ Improved safety profile due to reduced GvHD (immune rejection), CRS & secondary tumours as EVs don't replicate in the body
- ✓ **Improved efficacy** in solid tumours due to ability to infiltrate TME based on nano-size (10-9)
- ✓ Multiple doses and/or CAR-T follow-on or combination therapy
- Continuous manufacturing from immortalised cells enables off-theshelf (allogeneic) therapy for any patient
- ✓ Fast patient logistics and time-to-dose of ~1 week
- ✓ Reduced manufacturing and supply chain costs
- ✓ **Lower treatment cost** benefiting patients & healthcare system



# Clinical need & INOVIQ's CAR-EV targets

- Cancers for which there are <u>no</u> <u>targeted therapies</u> (TNBC)
- Cancers where Cell Therapy has limited access (glioblastoma)



# CAR-Exosomes | Target and kill cancer cells

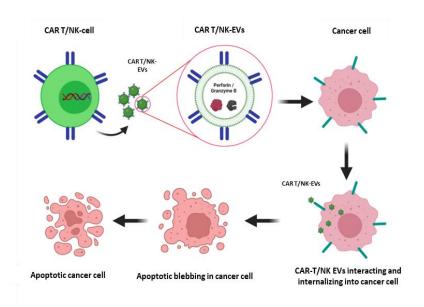


# CAR-EVs inherit the targeting and cytotoxic properties of their parent CAR-T or CAR-NK cells

- CAR-EVs are produced by CAR-T/NK cells
- CAR-EVs contains catalytic proteins (perforin and granzyme B)
- CAR-EVs interact and internalise into cancer cell
- Catalytic proteins from CAR-EVs induce cancer cell death (apoptosis)

## CAR-EVs for drug delivery

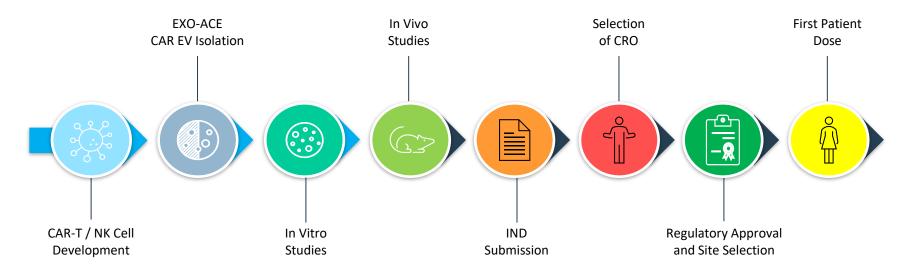
RNA and small molecules for combination therapy





# CAR-Exosomes | Development path





- ✓ Master cell banks established
- ✓ Cells engineered with CARs
- √ High purity & yield of CAR-EVs
- ✓ Scalable EXO-ACE EV isolation process
- ✓ In vitro PoC for CAR-T-EVs in BC cells
- ✓ In vitro PoC for CAR-NK-EVs in TNBC cells
- In vivo studies commencing 1H25
- Collaborations
   & contracts
   being
   established





# SubB2M Diagnostics | Glycan-binding technology and scientific rationale



Aberrant glycosylation (production of sugars) is a hallmark of cancer

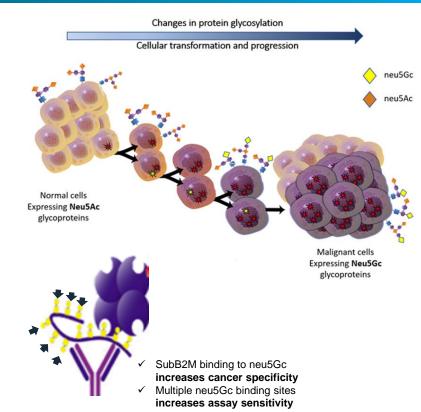
**Neu5Gc** is a sugar commonly found on cancer cells, but not healthy cells

**SubB2M** is an engineered protein that specifically binds neu5Gc

SubB2M is used in an **immunoassay format** to measure protein cancer biomarkers

Improves sensitivity and specificity for cancer detection (e.g. breast, ovarian, prostate, pancreatic & others)

Clinical applications for monitoring cancer treatment response and recurrence, general health assessment or high-risk screening









# Breast Cancer monitoring test | Path-to-market



#### **Breast Cancer**

- #1 cancer in women
- 2.3m new cases of breast cancer worldwide pa1
- 7.8m survivors (5-year)1

### **Unmet Medical** Need

- Non-invasive, earlier and more accurate tests required for monitoring breast cancer recurrence
- 10-40% of breast cancers recur within 5 years

#### **Market Potential**

- US\$4.3b global breast cancer diagnostics market<sup>2</sup>
- US\$668m TAM for breast cancer monitoring3

#### **Test & Data**

- NeuCA15-3 immunoassay detects CA15-3 cancer marker bound to neu5Gc4 to improve cancer specificity and sensitivity over existing CA15-3 test
- 81% sensitivity and 93% specificity for BC detection across all stages
- Detects key BC subtypes incl. HR+, HER2+ and TNBC & effective BC monitoring

#### **Intended Use**

• Aid in **monitoring** breast cancer treatment response and recurrence

## Go-to-Market Strategy

- LDT to IVD regulatory strategy (510k / De Novo process) with US FDA
- Partner LDT with CLIA-accredited laboratory
- Licence IVD to large diagnostics company

## **Development Path**

Feasibility

Assay development

Analytical validation

Clinical validation

Monitoring study

Bead-based assay transfer

In-clinic study

LDT partner

Completed

Completed

Ongoing

Completed

Completed

Underway

Commence 1H25

2025



# SubB2M Breast Cancer clinical data | Outperformed leading CA15-3 test



## Clinical Validation Study by Stage (2023)<sup>1</sup>

Retrospective, case-control, **clinical validation study** (n=483) to evaluate breast cancer detection by stage

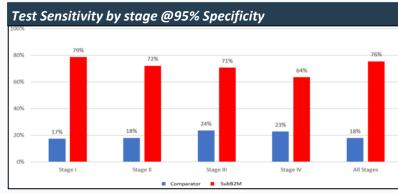
- ✓ **Detected all stages** of breast cancer with high accuracy (I IV)
- ✓ Detected common breast cancer types (IDC and ILC)
- ✓ Significantly outperformed a leading CA15-3 test (Roche Elecsys® CA15-3 II)

## Monitoring Study (2024)<sup>2</sup>

Retrospective, longitudinal, 2-arm **monitoring study** (n=277) to evaluate SubB2M CA15-3 test compared to Roche Elecsys<sup>®</sup> CA15-3 II (comparator)

- ✓ Detected main **breast cancer subtypes** (HR+, HER2+ and TNBC)<sup>3</sup> (n=159 pre-treatment samples)
- ✓ Established equivalence for BC monitoring (n=12 patients)
- ✓ Outperformed comparator identifying 19% more breast cancers

SubB2M CA15-3 vs Leading Existing Test						
<b>Breast Cancer</b>	SubB2M	Roche				
All Stages	CA15-3	Elecsys CA15-3 II				
AUC	0.93	0.70				
sensitivity	81%	37%				
specificity	93%	88%				
false negative rate	19%	63%				
false positive rate	7%	12%				
overall accuracy	87%	63%				



Breast cancer (n=241: I=75, II=72, 3=72, III=72, IV = 22) and healthy controls (n=242)



# Summary | Positioned for growth



4.5%



Proprietary **exosome platform** with multiple research, diagnostic and therapeutic applications



**Global distribution partner** for EXO-NET research tools to drive revenue growth



Multiple **evaluations** underway for EXO-NET / NEURO-NET exosome isolation, biomarker discovery and diagnostics



Clinically validated **SubB2M BC test** advancing to commercialisation



Pipeline of advanced diagnostics and high-value therapeutics for cancer



Leadership team with proven experience in exosome science, development and commercialisation

Financial information (ASX:IIQ)	
Ordinary shares <sup>1</sup>	111,526,702
Listed / Unlisted options <sup>1</sup>	9,753,913 / 8,791,66
52-week H/L <sup>1</sup>	A\$0.80-0.345
Share price <sup>1</sup>	A\$0.39
Market capitalisation <sup>1</sup>	A\$43.5m
Cash at bank <sup>2</sup>	A\$9.48m
Major shareholders (as at 12 December 2024)	
Merchant Funds Management	10.5%
Biotech Capital Management	6.4%
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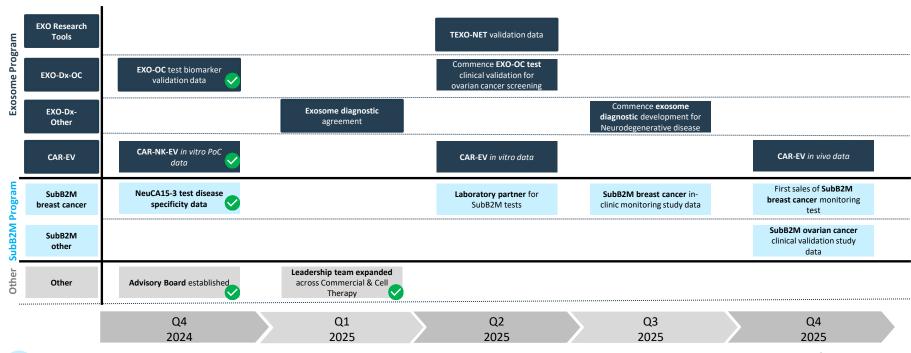
## IIQ 12-month share price performance<sup>1</sup>

**David Williams** 



# Future catalysts | Developing better healthcare solutions









# Contacts



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## Board & Management | Corporate, scientific and commercial expertise





DAVID WILLIAMS Non-Executive Chairman

Experienced biotechnology director and investment banker with extensive strategic, corporate and financial markets experience.

Currently Chairman PolyNovo Ltd, Chairman of RMA Global Ltd and Managing Director of corporate advisory firm Kidder Williams Ltd.

Previously Chairman and major shareholder Medical Developments International Ltd. Major shareholder Healthily Pty Ltd.



Non-Executive Director Healthcare and biotechnology director

with extensive diagnostics industry experience.

Currently NED AnteoTech Ltd.

Previously Managing Director Roche Diagnostic Systems (Oceania), MD/CEO Biosceptre international Ltd and MD/CEO of Anteo Diagnostics Ltd.



MAX JOHNSTON Non-Executive Director

Healthcare industry director and international business leader with extensive experience across medtech, pharmaceuticals, consumer healthcare and consumer goods.

Currently NED Neurotech International. Previously President and CEO of Johnson & Johnson Pacific, Chairman of AusCann Ltd, NED of PolyNovo Ltd, Medical Developments International Ltd, Tissue Repair Ltd and CannPal Animal Therapeutics Ltd.



PHILIP POWELL Non-Executive Director

Healthcare industry director and chartered accountant with extensive investment banking experience specialising in capital raisings, IPOs, mergers and acquisitions and other transactions across pharma, food and agriculture.

Previously at OAMPS Ltd and Arthur Andersen, and NED at RMA Global Ltd, Polynovo Ltd and Medical Developments International Ltd.



MARY HARNEY Non-Executive Director

Experienced Non-Executive Director and Chief Executive bringing a deep understanding of applied life science research, in addition to experience in biopharmaceutical regulatory affairs and commercialisation.

Current Chair of Oncology One Pty Ltd. Previously Chair of Race Oncology (ASX: RAC) and Microbio Limited.



**DR LEEARNE HINCH BVMS MBA Chief Executive Officer** 

Biotechnology CEO with a proven track record in corporate strategy, capital raising, product development, business development and partnering across diagnostics, medical devices, therapeutics and animal health.

Past leadership and consulting roles in ASXlisted biotechnology, multinational and private companies including Eustralis Pharmaceuticals, HealthLinx, OBJ, Holista Colltech, Chemeg, Virbac and Mars.



DR GREG RICE PhD MHA Chief Scientific Officer

Internationally recognised, award-winning scientist with over 35 years' experience and a successful track record in oncology research, exosome science, biomarker discovery, and diagnostics development.

Previous leadership roles in academia and industry including at The University of Queensland Centre for Clinical Research, Baker Heart Institute, University of Melbourne, Monash University and HealthLinx.



MARK EDWARDS BACC CA **CFO & Company Secretary** 

Experienced finance executive with expertise in financial leadership and management, corporate governance, investor relations and corporate transactions.

Previous senior roles in ASX listed pharmaceutical, medical device and healthcare companies, including Medical Developments International and Cogstate.



EMMA BALL PhD MBA GAICD **Chief Commercial Officer** Commences 22 Apr-25

Experienced biotechnology commercialisation executive with expertise in business development, licensing, and strategic partnerships across therapeutics, vaccines and diagnostics.

Currently Non-Executive Chair of BioMelbourne Network. Previous senior business development/ licensing roles in multinational biotechnology companies CSL Ltd and Illumina Inc.

# Advisory Board | Renowned clinical researchers and oncologists





**PROF MILES PRINCE AM**Clinical Haematologist &
Oncologist

Leading Clinical Haematologist and Oncologist and Professor at both Melbourne and Monash universities. He is an NHMRC Investigator Fellow and has been principal investigator of over 100 clinical trials including targeted therapeutics (CAR-T therapy) for haematological conditions and cancers.



PROF PHIL DARCY
Principal Research Fellow

Group Leader of the Cancer Immunotherapy Laboratory at the Peter MacCallum Cancer Centre and NHMRC Principal Research Fellow, focusing on novel T cell-based immunotherapy approaches for cancer in preclinical mouse models and clinical translation.



PROF CARLOS SALOMON
NHMRC Investigator Fellow

Director of the University of Queensland Centre for Extracellular Vesicle Nanomedicine, Head of the Translational Extracellular Vesicles in Obstetrics and GynaeOncology Group and NHMRC Investigator Fellow, specialising in exosome biology and its clinical translation to diagnostics and therapeutics for ovarian cancer and obstetrical syndromes.



**DR JAMES MCCRACKEN**Medical Oncologist

Leading Medical Oncologist specialising in breast cancer treatment at Epworth Healthcare and the Peter MacCallum Cancer Centre. His research interests include the field of liquid biopsies for cancer to personalise treatment and minimise toxicity.

