# **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
<b>Registration:</b>	click the webinar link here

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	David Williams
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 <u>www.inoviq.com</u>.





# **INOVIQ** overview

# Next-generation cancer diagnostics and therapeutics



19<sup>th</sup> March 2025



**ASX: IIQ** 



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## INOVIQ Overview | Next generation diagnostics and therapeutics





- 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











*Exosome* = *EV* = *Extracellular Vesicles*; *ICC* = *Immunocytochemistry*; *IVD* = *In Vitro Diagnostic*; *LDT* = *Laboratory-Developed Test*; *RUO* = *Research Use Only* 1. *Global Exosome Research Market* (2021 - 2026) (researchandmarkets.com); 2. *Breast Cancer Diagnostics Market Size & Share Report* 2030 (grandviewresearch.com);

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3. Ovarian Cancer Diagnostics Market Size, Share, Trends | Forecast 2032 (acumenesearchandconsulting.com); 4. Breast Cancer Therapeutics Market Growth, Trends & Dynamics, 2027 (fortunebusinessinsights.com)



## 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





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/day1

**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** 

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2. ISEV (ASX: 19/5/23), ANZSEV (ASX: 10/11/23) and AMP (12/11/23); 3. Immunoaffinity-enriched salivary small extracellular vesicles in periodontitis (oaepublish.com); 4. High throughput Surface Epitope Immunoaffinity Isolation of EVs (oup.com)







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</i> & <i>monitoring MRD</i> . Mid-vol biomarker discovery, companion diagnostics & target identification.	14
Clinical/ Hospital	Key customers requiring a <i>scalable EV</i> <i>isolation solution</i> . Higher-vol sales as projects progress thru development to registration to market.	16
TOTAL		51





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

- UQ<sup>1</sup> 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 set<sup>2</sup>
- 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>

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1. The University of Queensland (UQ) (ASX: 1/4/22); 2. Research supported by an Ovarian Cancer Research Foundation (OCRF) grant; 3. Research supported by \$2.7m Medical Research Future Fund (MRFF); 4. Biomarker validation study (ASX: 3/12/24); 5. INOVIQ-UQ Umbrella Research & Option Agreement





#### Ovarian Cancer screening test | Path-to-market





1 <u>2032 (www.acumenresearchandconsulting.com)</u>; 3. Based on 538k tests pa @\$600/test for OC high-risk screening twice yearly in US, EU5 and AU.; 4. Biomarker validation study (ASX: 3/12/24)





- 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







- 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<sup>-9</sup>)
- ✓ 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





✓ Cells engineered with CARs  ✓ High purity & ✓ In vitro Po yield of CAR CAR-T-EVs
 BC cells
 ✓ Scalable EXO ✓ In vitro Po
 ACE EV
 CAR-NK-EV
 isolation
 TNBC cells

 CAR-T-EVs in
 commencing

 BC cells
 1H25

 ✓ In vitro PoC for
 Collaborations

 CAR-NK-EVs in
 & contracts

 TNBC cells
 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



<ul> <li><b>#1 cancer in women</b></li> <li>• 2.3m new cases of breast cancer worldwide pa<sup>1</sup></li> </ul>		Development Path	
	• 7.8m survivors (5-year) <sup>1</sup>	Feasibility Completed	
Unmet Medical Need	<ul> <li>Non-invasive, earlier and more accurate tests required for monitoring breast cancer recurrence</li> <li>10-40% of breast cancers recur within 5 years</li> </ul>	Assay development Completed	
	• US\$4.3b global breast cancer diagnostics market <sup>2</sup>	Analytical Ongoing validation	
Market Potential	• US\$668m TAM for breast cancer monitoring <sup>3</sup>	Clinical Completed	
Test & Data	<ul> <li>NeuCA15-3 immunoassay detects CA15-3 cancer marker bound to neu5Gc<sup>4</sup> to improve cancer specificity and sensitivity over existing CA15-3 test</li> <li>81% sensitivity and 93% specificity for BC detection across all stages</li> <li>Detects key BC subtypes incl. HR+, HER2+ and TNBC &amp; effective BC monitoring</li> </ul>	Monitoring study Completed	
		Bead-based assay transfer Underway	
Intended Use	<ul> <li>Aid in monitoring breast cancer treatment response and recurrence</li> </ul>	In-clinic study O Commence 1H25	
Go-to-Market Strategy	<ul> <li>LDT to IVD regulatory strategy (510k / De Novo process) with US FDA</li> <li>Partner LDT with CLIA-accredited laboratory</li> <li>Licence IVD to large diagnostics company</li> </ul>	LDT partner O 2025	

510k = FDA clearance for Class II device; CLIA = Clinical Laboratory Improvement Amendments (high-complexity tests) ; IVD = In Vitro Diagnostic; LDT = Laboratory Developed Test; 1. https://gco.iarc.fr/today/home; 2. Breast Cancer Diagnostics Market Size & Share Report 2030 (grandviewresearch.com); 3. Based on 4.5m tests pa @\$150/test for BC monitoring in US, EU5 and AU; 4. Neu5Gc = the sialic acid, N-qlycolylneuraminic acid



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

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

- $\checkmark$  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<sup>®</sup> 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)
- $\checkmark$  Outperformed comparator identifying **19% more breast cancers**

SubB2M CA15-3 vs Leading Existing Test			
Breast Cancer	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





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 / 8,791,667
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%
David Williams	4.5%
IIQ 12-month share price performance <sup>1</sup>	
0.800	5.0





Future milestones are forward-looking and may change based on study results, funding, partnering and priorities



# 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.



#### 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.





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.



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.



#### 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.



MAX JOHNSTON

Healthcare industry director and

international business leader with

and consumer goods.

Therapeutics Ltd.

extensive experience across medtech, pharmaceuticals, consumer healthcare

Currently NED Neurotech International.

Johnson & Johnson Pacific, Chairman of

Medical Developments International Ltd,

Tissue Repair Ltd and CannPal Animal

Previously President and CEO of

AusCann Ltd, NED of PolyNovo Ltd,

#### 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.



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.



#### 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. 





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.



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.