

# **AGM Presentation**

28 November 2024

Next-generation diagnostics and therapeutics



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### INOVIQ Overview | Next generation diagnostics and therapeutics



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# Exosome powered

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



# Disruptive technology

Proprietary exosome and SubB2M technologies



# Products in market

Exosome research tools and bladder cancer test generating revenues



### Deep pipeline

Differentiated, multistage exosome research tool, diagnostic and therapeutic pipeline for cancer



## Excellent clinical data

Data showing superior exosome isolation, accurate cancer detection and cancer killing activity



# Partnering for growth

Commercialization via partnering with distributors, clinical laboratories and pharma

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0.10

Nov-23

| Financial information (ASX:IIQ)                   |  |  |  |
|---|--|--|--|
| Ordinary shares <sup>1</sup>                      | 111,526,702  |  |  |
| Listed / Unlisted options <sup>1</sup>            | 9,378,913 / 7,824,889                                |  |  |
| 52-week H/L <sup>1</sup>                          | A\$0.92-0.42   |  |  |
| Share price <sup>1</sup>                          | A\$0.44  |  |  |
| Market capitalisation <sup>1</sup>                | isation <sup>1</sup> A\$49.1m                        |  |  |
| Cash at bank <sup>2</sup>                         | A\$10.02m  |  |  |
| Major shareholders (as at 27 November 2024)       | )  |  |  |
| Merchant Funds Management 10.5%                   |  |  |  |
| Biotech Capital Management                        | 6.4%   |  |  |
| David Williams 4.5%                               |  |  |  |
| IIQ 12-month share price performance <sup>1</sup> |  |  |  |
| 0.90<br>0.80<br>0.70<br>0.60<br>0.50<br>0.40      | 5.0<br>4.5<br>4.0<br>3.5<br>3.0<br>2.5<br>2.0<br>1.5 |  |  |

May-24

Mar-24

Volume (m) (RHS)

Jul-24

Last Close (LHS)

Sep-24

### 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

US\$661m1



# **Diagnostics**

**Pipeline** 

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

US\$6.1b2,3



#### **Therapeutics**

Exosome therapeutics to target and kill solid tumours

US\$55.3b4



### FY24 Achievements | Strong development & commercial progress



#### **Commercial**

| • Jul-23 | EXO-NET® Global Joint Marketing Agreement with Promega                                   |
|----------|--|
| • Sep-23 | EXO-NET® Services License and Supply Agreement with ResearchDx in US                     |
| • Oct-23 | NEURO-NET <sup>™</sup> provisional patent application filed                              |
| • Dec-23 | First EXO-NET® Research Collaboration with Biotech to evaluate use in exosome diagnostic |
| • Mar-24 | EXO-ACE <sup>™</sup> provisional patent application filed                                |
| • Apr-24 | EXO-NET® Global Supply and Distribution Agreement with Promega                           |

#### **Exosome Programs**

| <ul> <li>Aug-23</li> </ul> | EXO-OC test data demonstrating equivalence of EXO-NET® |
|----------------------------|--|
|                            | isolated exosomes from plasma and serum                |

• Nov-23 EXO-NET® data presented at AMP and ANZSEV

 May-24 EXO-NET® paper published in Biology Methods & Protocols EXO-NET® data presented at ISEV

 Jun-24 NEURO-NET<sup>TM</sup> validation data in Alzheimer's Disease CAR-Exosome therapy in vitro Proof-of-Concept in breast cancer cells

• Aug-24 NEURO-NET<sup>TM</sup> validation data in Parkinson's Disease

#### **Corporate & Finance**

| <ul> <li>Nov-23</li> </ul> | Board expanded with David Williams appointed Chair |
|----------------------------|--|
| • Jul-24                   | A\$9.4m capital raised                             |
|                            |  |

• Sep-24 Board expanded with Mary Harney appointed NED

#### **SubB2M Programs**

- Feb-24 NEU-CA15-3 test clinically validated to detect key breast cancer subtypes and be effective for BC monitoring
- Apr-24 NEU-CA125 analytical validation completed in ovarian cancer samples



### **EXO-NET Commercial Progress**

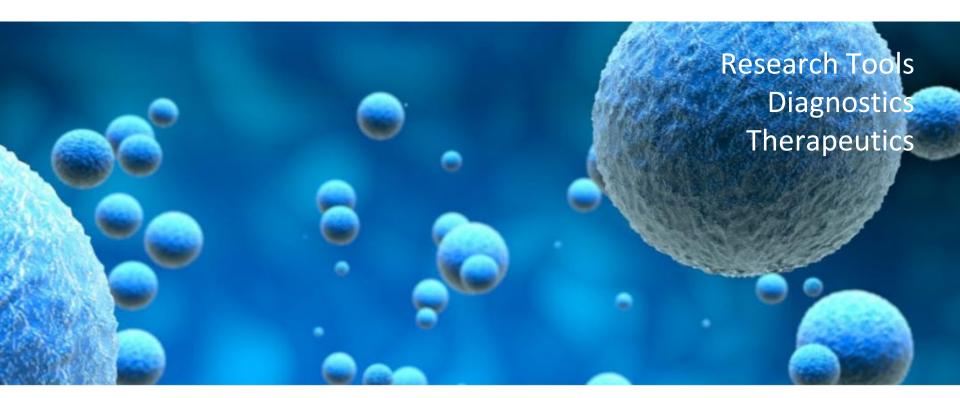


- Total # customers: as at 31st Oct-24
  - Promega partnership expected to be a key driver of EXO-NET revenues
  - First order received Jun-24, with 33 customers won in 4 months (> 8/m or 2/w) from US, EU and Asia
- Applications: Oncology, Neurology, Cardiac Conditions, Transplant Rejection, Sepsis & fundamental EV research
- Product development: Exosome research tool portfolio expanded
  - NEURO-NET for isolating exosomes from brain tissue
  - TEXO-NET for capturing exosomes from cancer
  - Custom NETs for isolating specific exosomes for agreed customer indications
  - Combination products: Promega optimising EXO-NET/RNA combination products that integrate with Maxwell systems and consumables to provide flexible, scalable solutions
- Outlook:
  - Engaging with academia and industry worldwide to secure collaborations and sales of EXO-NET and combination products to enable development of more accurate and reliable exosome diagnostics
  - Progressing multiple evaluations of EXO-NET and NEURO-NET for biomarker discovery and diagnostic development for cancer, cardiology and neurological diseases
  - Successful evaluations are expected to drive sales of EXO-NET in exosome diagnostic projects over the next 12-months and underpin revenue growth

| Customer<br>type        | Profile  | #  |
|-------------------------|--|----|
| Academic/<br>Government | Exosome KOLs validating EXO-NET across expanded applications & delivering <i>publications &amp; presentations</i> . Small-vol biomarker discovery & validation data. | 18 |
| Pharma/<br>Biotech      | Key customers requiring a <i>scalable EV isolation solution</i> . Mid-vol biomarker discovery and diagnostic development.  | 7  |
| Clinical/<br>Hospital   | In-market exosome diagnostics. High-<br>vol diagnostic sales.  | 8  |
| TOTAL                   |  | 33 |



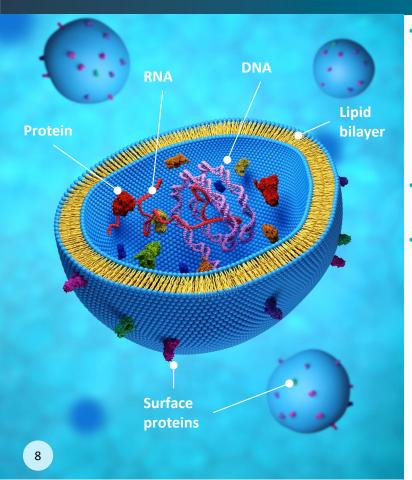
# **Exosome Platform**



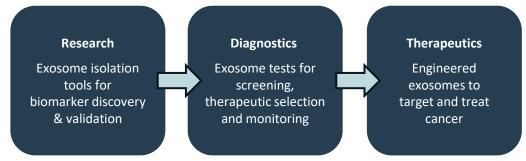


### Exosomes | Significant diagnostic and therapeutic potential





- **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>

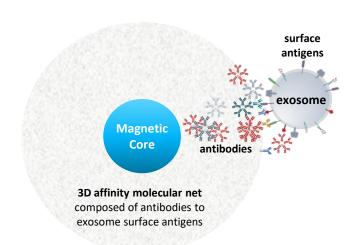
**Data published validating EXO-NET** utility in cancer, neurodegenerative, periodontitis, placental and inflammatory diseases<sup>2,3,4</sup>

**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 now validated & available



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

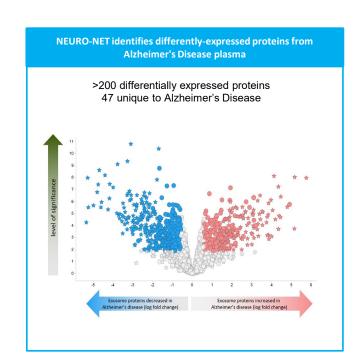
Designed using **proprietary antibody combination** that isolates exosomes secreted from brain cells (neurons, microglia, oligodendrocytes & astrocytes)

**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 expands INOVIQ's exosome capabilities to develop new diagnostics for neurological conditions. Brain-derived exosomes hold enormous potential for diagnosis and treatment of neurological diseases.



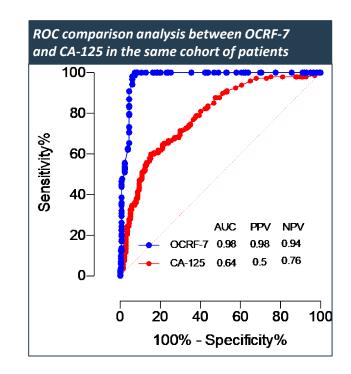


### Exosome Diagnostics | Academic collaboration validating EXO-NET



### 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 retrospective casecontrol study achieving over 90% accuracy for detection of stage I / II ovarian cancer
- OCRF-7 biomarker algorithm was developed in a 465sample discovery set<sup>2</sup>
- Exosome isolation initially performed using SEC (not compatible with pathology lab workflow) and successfully transferred to EXO-NET
- Biomarker validation study underway using EXO-NET exosome isolation on 500-sample independent set<sup>3</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<sup>4</sup>







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



#### **Ovarian Cancer**

- #8 cancer in women & deadliest gynaecological cancer
- 314k new cases of ovarian cancer worldwide pa<sup>1</sup>
- 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<sup>3</sup>
- Earlier and more accurate tests required for screening high-risk women<sup>3</sup>

#### **Market Potential**

- US\$1.7b global ovarian cancer diagnostics market<sup>2</sup>
- US\$323m TAM based on 538k tests pa @\$600/test for OC high-risk screening twice yearly in US, EU5 and AU<sup>4</sup>
- US\$32b TAM based on 54.8m tests pa @\$600/test for OC average-risk screening biennially in US, EU5 and AU<sup>4</sup>

#### **Test & Data**

- Exosome multi-marker test validated in a 465-sample retrospective case-control study with over 90% accuracy for detection of stage I / II ovarian cancer<sup>5</sup>
- Biomarker validation data from 500-sample independent set expected Dec-24

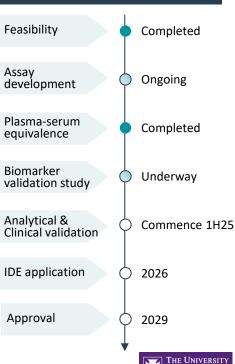
#### **Intended Use**

• Screening to detect ovarian cancer in asymptomatic women

#### Go-to-Market Strategy

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

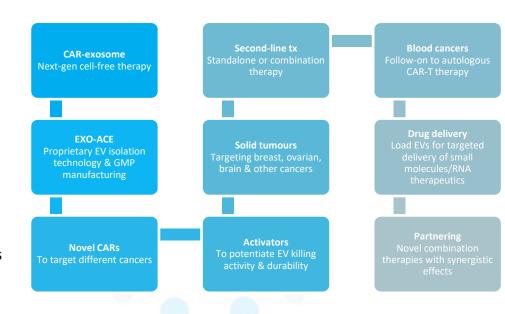
### **Development Path**



### Exosome Therapeutics | Next-gen cell-free therapy



- 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
- INOVIQ is developing weaponised exosomes engineered to target and kill solid tumours
- CAR-exosomes inherit the targeting and cytotoxic properties of their parent cells to kill cancer
- Next-gen "off-the shelf" cell-free therapy for solid tumours
- Potential safety, efficacy and cost advantages over autologous CAR-T therapy



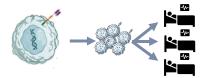


### CAR-Exosomes | Allogenic EV-based therapy with multiple advantages



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

- ✓ **Improved 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 enabling 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 per patient benefiting patients & healthcare system
- ✓ Improved safety profile due to reduced GvHD (immune rejection), CRS & secondary tumours as EVs don't replicate in the body



# 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 <u>limited access</u> (glioblastoma)



### CAR-T-EVs | A promising alternative to cell-based therapies

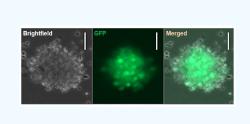


### CAR-EV generation, enrichment, EV characterisation and functional readout

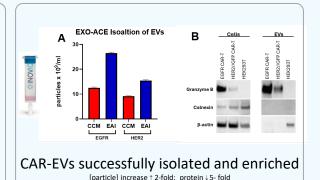
- CAR-T cells targeting EGFR were cultured and EVs isolated from cell-conditioned medium by ionexchange chromatography (EXO-ACE™)
- EGFR targeting CAR-EVs reduced MCF-7 and K562 cell viability by 70% & 40%, respectively

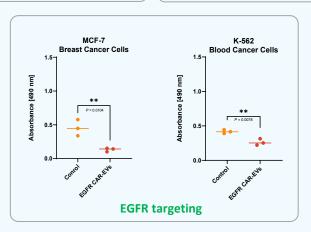


(MTS Assay



T-Cells successfully transduced

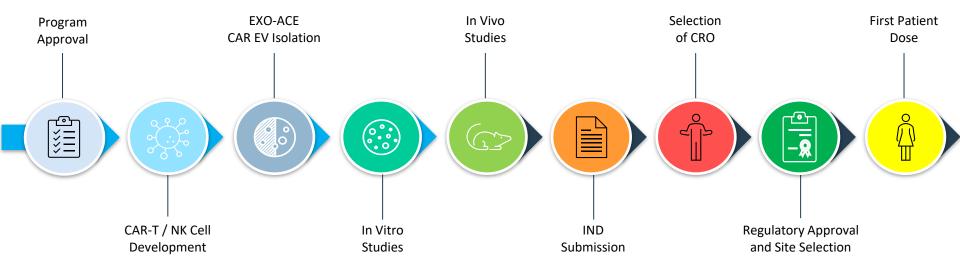






### CAR-Exosome Therapy | Development path





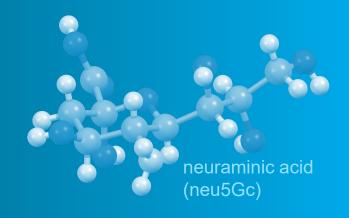
- ✓ Master cell banks established
- ✓ Cells engineered with CARs
- ✓ High purity & yield of CAR-EVs
- ✓ Scalable EXO-ACE EV isolation process
- ✓ In vitro PoC for CAR-T-EVs in BC cell line
- In vitro PoC for CAR-NK-EVs expected Dec-24
- In vivo studies commencing
   1H25
- Collaborations
   & contracts
   being
   established





# **SubB2M Cancer Diagnostics**

Improved cancer detection and monitoring





### SubB2M | Glycan-binding technology and scientific rationale



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

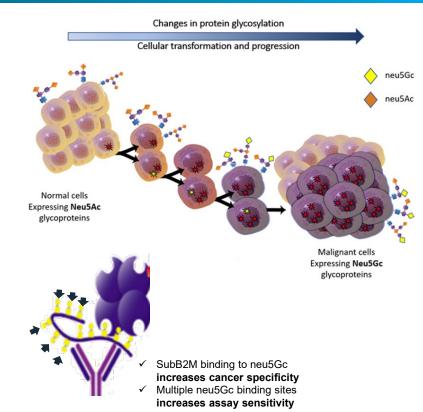
**Neu5Gc** is a sugar commonly found on cancer cells, but not healthy cells

**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 TAM3

#### **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

#### **Intended Use**

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

#### Go-to-Market Strategy

- LDT to IVD regulatory strategy (510k / PMA 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

Ongoing

Completed

Completed

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

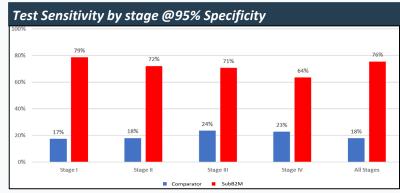
- ✓ **Detected all stages** of breast cancer with high accuracy (I IV)
- ✓ Detected **common breast cancer types** (IDC and ILC)
- ✓ Significantly outperformed a leading CA15-3 test (Roche Elecsys® CA15-3 II)

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

Retrospective, longitudinal, 2-arm monitoring study (n=277) to evaluate SubB2M CA15-3 test compared to Roche Elecsys® 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

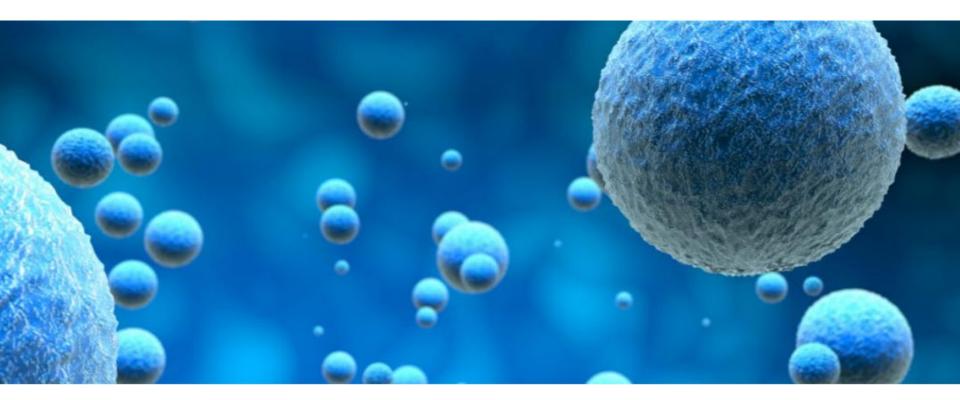
| SubB2M CA15-3 vs Leading Existing Test |        |                   |  |
|--|--------|-------------------|--|
| Breast Cancer                          | SubB2M | Roche             |  |
| All Stages                             | CA15-3 | Elecsys CA15-3 II |  |
| AUC                                    | 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)



# Outlook & Catalysts





### Outlook | 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



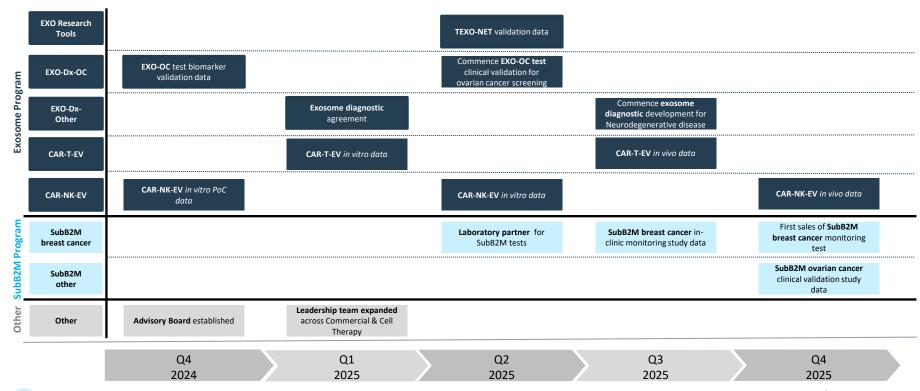
Leadership team with proven experience in exosome science, development and commercialisation





### Future catalysts | Developing better healthcare solutions









## Contacts



**David Williams** Non-Executive Chairman

e. dwilliams@kidder.com.au



**Dr Leearne Hinch BVMS MBA**Chief Executive Officer

e. lhinch@inovig.com



**Prof Gregory Rice PhD MHA**Chief Scientific Officer

e. grice@inoviq.com

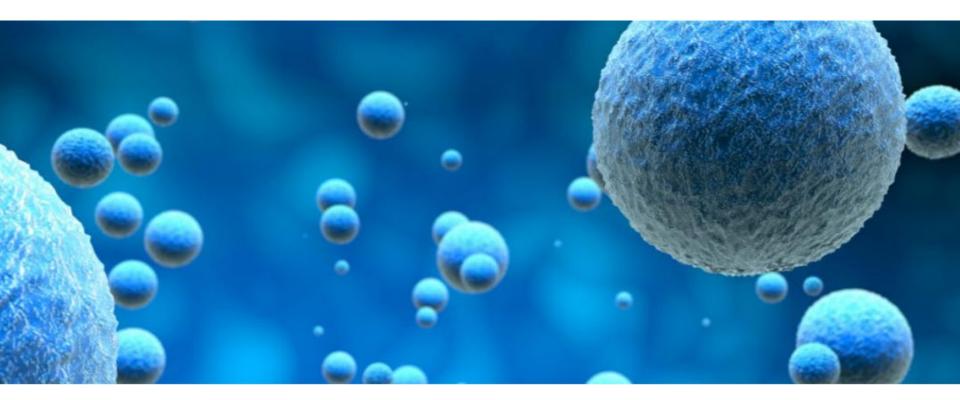


Mark Edwards CA B Acc CFO & Company Secretary

e. medwards@inoviq.com



# **Appendices**





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





strategic, corporate and financial

Currently Chairman PolyNovo Ltd,

Chairman of RMA Global Ltd and

Previously Chairman and major

shareholder Medical Developments

International Ltd. Major shareholder

Managing Director of corporate advisory

markets experience.

firm Kidder Williams Ltd.

Healthily Pty Ltd.

DAVID WILLIAMS Non-Executive Chairman



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 GEOFF CUMMING



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 ASX-listed 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.



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



|                | Product             | Indication and Use                                       | <b>Development Stage</b>     | <b>Next Milestones</b>            | <b>Market Opportunity</b>   |
|----------------|---------------------|--|------------------------------|-----------------------------------|-----------------------------|
| Research Tools | EXO-NET             | Biomarker Discovery & Diagnostics Pan EV Capture         | In-Market<br>RUO             | Sales Growth &<br>Collaborations  |                             |
|                | NEURO-NET           | <b>Neurology Diagnostics</b><br>Brain-Derived EV Capture | Validation<br>RUO            | Collaborations                    | US\$661m                    |
|                | TEXO-NET            | Oncology Diagnostics<br>Tumour-Derived EV Capture        | Verification<br>RUO          | Validation Data<br>1H25           |                             |
| Diagnostics    | htert ICC1          | <b>Bladder Cancer</b><br>Adjunct to Cytology             | In-Market<br>IVD-Class 1 USA |                                   | <us\$20m< th=""></us\$20m<> |
|                | neuCA15-3           | Breast Cancer<br>Monitoring                              | Clinical Validation<br>LDT   | In-clinic Monitoring data<br>2H25 | US\$4.3b                    |
|                | neuCA125            | Ovarian Cancer<br>Monitoring                             | Assay Development<br>LDT     | Clinical Validation<br>2026       |                             |
|                | EXO-OC <sup>2</sup> | Ovarian Cancer<br>Screening                              | Assay Development IVD        | Biomarker Validation<br>Dec-24    | US\$1.7b                    |
| Therapeutics   | EEV-001             | Breast Cancer<br>CAR-Exosome Therapy                     | Discovery                    | CAR-NK-EV In Vitro data<br>Dec-24 | US\$55.3b                   |

