

# **MST Access Diagnostics Forum notice**

**Melbourne, Australia, 5 December 2022:** INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**) advises that CEO Dr Leearne Hinch will deliver the attached presentation to investors and shareholders at the **MST Access Diagnostics Forum** on 6 December 2022.

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

Date:Tuesday, 6 December 2022Time:10:40 AM AEDTRegistration:MST Access Diagnostics Forum

Authorised for release by Company Secretary, Mark Edwards.

- ENDS -

#### **COMPANY CONTACTS**

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#### **ABOUT INOVIQ LTD**

INOVIQ Ltd (ASX:IIQ) (**INOVIQ**) is developing and commercialising next-generation exosome capture tools and precision diagnostics to improve the diagnosis and treatment of cancer and other diseases. The Company has commercialised the EXO-NET pan-exosome capture tool for research purposes and the hTERT test as an adjunct to urine cytology testing for bladder cancer. Our cancer diagnostic pipeline includes blood tests in development for earlier detection and monitoring of ovarian, breast and other cancers. For more information on INOVIQ, see <u>www.inovig.com</u>.

#### FORWARDING LOOKING STATEMENTS

This announcement contains certain 'forward-looking statements' within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as 'may', 'should', 'expect', 'anticipate', 'estimate', 'scheduled' or 'continue' or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.





# **Investor Presentation**

6 December 2022



MST Access Diagnostics Forum ASX: IIQ

#### Disclaimer



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# INOVIQ highlights



Next-generation exosome capture tools and precision diagnostics

Patented technology platforms for biomarker isolation and detection

Products in-market for exosome research & bladder cancer

Multi-product cancer diagnostics pipeline targeting large global markets

Compelling early data in breast and ovarian cancers

Multiple key inflection points over next 12 months

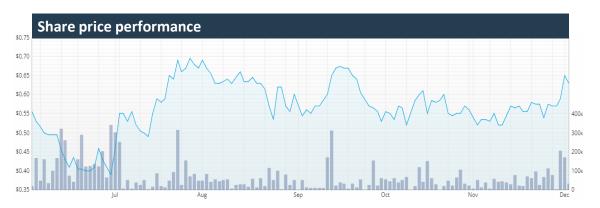


# INOVIQ snapshot



Financial information (ASX:IIQ)		
Ordinary shares <sup>2</sup>	92,018,702	
Listed options <sup>2</sup>	5,909,965	
Share price <sup>2</sup>	A\$0.630	
Market capitalisation <sup>2</sup>	A\$58.0m	
Cash at bank <sup>1</sup>	A\$13.5m	
Ave monthly cash burn <sup>3</sup>	A\$607k	

Major shareholders (as at 2 December 2022)		
Merchant Funds Mgt Pty Ltd	14.2%	
Moggs Creek Pty Ltd 5.3%		
Dr Irmgard Irminger-Finger	3.8%	
Peter Gunzburg	2.0%	
ТОР 20	35.6%	



Board and Management	
Dr Geoff Cumming	Non-Executive Chairman
Mr Robert (Max) Johnston	Non-Executive Director
Mr Philip Powell	Non-Executive Director
Professor Allan Cripps AO	Non-Executive Director
Dr Leearne Hinch	Chief Executive Officer
Dr Greg Rice	Chief Scientific Officer
Mr Mark Edwards	Chief Financial Officer & Company Secretary



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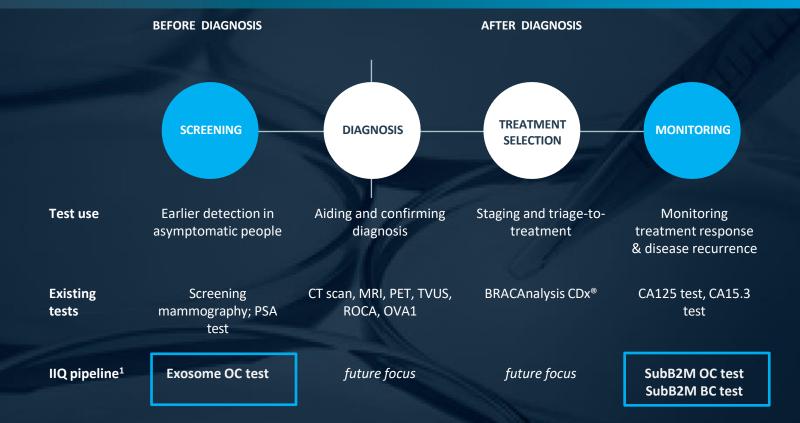


PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL DEVELOPMENT	REGISTRATION
hTERT <sup>1</sup>	Bladder Cancer	ICC	Adjunct to cytology		-	•	★ In-market
EXO-NET-RUO	Exosome Capture	Device	Research tool			•	★ In-market
Exosome-OC <sup>2</sup> (OCRF-7)	Ovarian Cancer	Multiomic	Screening	•			
SubB2M-BCM	Breast Cancer	Immunoassay	Monitoring		•		2023
SubB2M-OCM	Ovarian Cancer	Immunoassay	Monitoring		•		2023
SubB2M-SPR	Multi-cancer	SPR	Risk assessment		-•		
SubB2M-PCS	Prostate Cancer	Immunoassay	Detection	•			
SubB2M-PaC	Pancreatic Cancer	Immunoassay	Detection	-•			
BARD1-Ovarian <sup>3</sup>	Ovarian Cancer	Immunoassay	Detection	•			
BARD1-Breast <sup>3</sup>	Breast Cancer	Immunoassay	Detection				

\*RUO = Research Use Only; ICC = Immunocytochemistry; 1. Adjunct to urine cytology to assist the detection of bladder cancer; 2 Umbrella Research & Option Agreement with UQ, 3. Progression subject to completion of review (ASX: 28/3/22)

# Indications for Use | Tests for different cancers and uses in the diagnostic pathway







### **Ovarian Cancer | Overview**



Stage 4

Spread to other

organs

15%

- **#8** most common cancer & **#1** gynaecological cancer • deaths in women worldwide
- UNMET NEED for earlier and more accurate tests for OC detection and monitoring

prevalence 823k \$1.9b<sup>1</sup> Incidence **314k OVARIAN** deaths 207k





### Current Standard of Care<sup>3</sup>

Stage 1

Confined to

ovaries

95%

Normal

Healthy ovaries

100%

Screening	No tests recommended to SCREEN average-risk, asymptomatic women for ovarian cancer
Monitoring	CA125 blood test approved to MONITOR treatment response and recurrence in women with ovarian cancer

Stage 2

Spread within

pelvis

70%

Stage 3

Spread within

abdomen

25%

1.: GLOBOCAN (IARC) 2020; & https://www.globenewswire.com/news-



release/2019/08/07/1898453/0/en/Ovarian-Cancer-Diagnostics-Market-Size-Worth-US-1-8-Bn-by-2026.html 2. www.cancer.org; www.cancer.net; www.cancerresearchuk.org; 3. USPSTF, ACS, ACOG, AGDH

5-year Survival by Stage at Diagnosis<sup>2</sup>

CANCER

# OC Screening | Exosomal ovarian cancer screening test



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

- UQ's OCRF-7 validated in a retrospective casecontrol study achieving over 90% accuracy for detection of stage I / II ovarian cancer<sup>3</sup>
- UQ project funded via a \$2.7m MRFF<sup>2</sup> grant
- INOVIQ has the **exclusive option to license** the development and commercialisation rights
- Meets critical need for early detection of ovarian cancer to improve treatment options, women's health outcomes and help save lives

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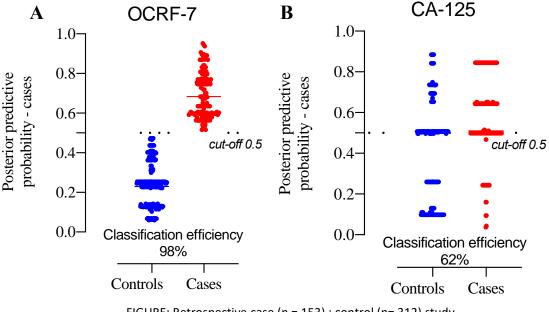


FIGURE: Retrospective case (n = 153) : control (n= 312) study comparing accuracy of OCRF-7 algorithm to CA-125 assay





#### **Next-steps**

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- 1. Ovarian Cancer 97 Study: To establish that EXO-NET is fit-for-purpose for the downstream analysis of plasma extracellular vesicle associated microRNA and protein and for use in MRFF Ovarian Cancer Screening Study (UQ)
- 2. OC 250 Study: Analytical Validation study including plasma and serum comparison
- OC 3000 Study: Clinical Validation study using 3000 samples obtained from the UKCTOCS study (Case : control ratio = 1:2)

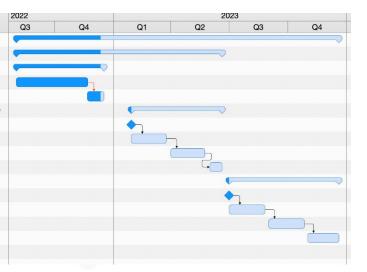


▼ EV-based Earlier Detection for Ovarian Cancer

EXO-NET Isolation Fit-for-Purpose
 Ovarian Cancer 97 study Case-control study

Downstream miRNASeq & LC MS/MS Data analysis & Modeling

- Ovarian Cancer 250 Analytical Validation Study UCL samples plasma vs serum received by UQ EV isoaltion of matched plasma and serum Biomarker assay and data comparisonn Data Analysis & Report
- Ovarian Cancer 3000 Study
  UCL samples received
  EV isolation
  Biomarker Analysis
  Data analysis and reporting



### Breast Cancer | Overview

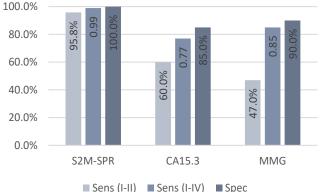


- #1 most common cancer & #1 cancer deaths in women worldwide
- UNMET NEED for earlier and more accurate tests for BC detection and monitoring

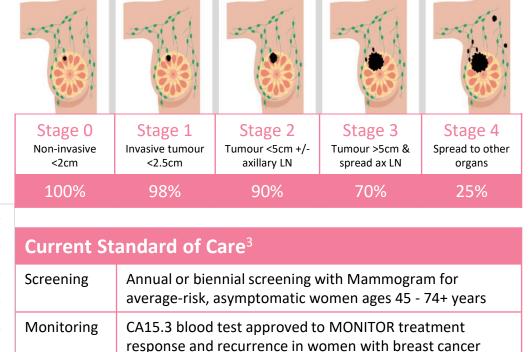
\$4.2b<sup>1</sup> prevalence 7.8m BREAST CANCER deaths 685k

-

85%



### 5-year Survival by Stage at Diagnosis<sup>2</sup>



1. <u>https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market</u> & GLOBOCAN (IARC) 2020; 2. www.cancer.org; www.cancer.net; www.cancerresearchuk.org. 3. USPSTF, ACS, ACOG, AGDH



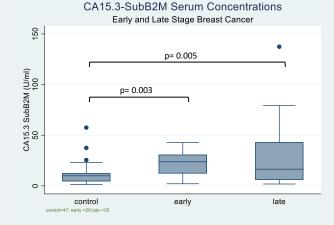
# BC Monitoring | SubB2M-based Breast Cancer monitoring test



- SubB2M-based immunoassay development, optimisation and validation underway at ResearchDx<sup>1,2</sup>
- Commenced breast cancer clinical study (BC95) to evaluated performance of SubB2M-CA15.3 by cancer stage
- Interim data are encouraging and indicate that both early- and late-stage breast cancer samples can be discriminated from cancer-free (controls) samples.
- Next step is to establish reproducibility of the assay

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#### BC 95 Study: Breast Cancer Clinical Study



Kruskal-Wallis Test chi<sup>2</sup> = 13.7, p = 0.001, Pair-wise comparisons – Dunn's Test (Bonferroni) .The median value and interquartile ranges are presented.





#### Intended use: A blood test to aid in monitoring breast cancer recurrence

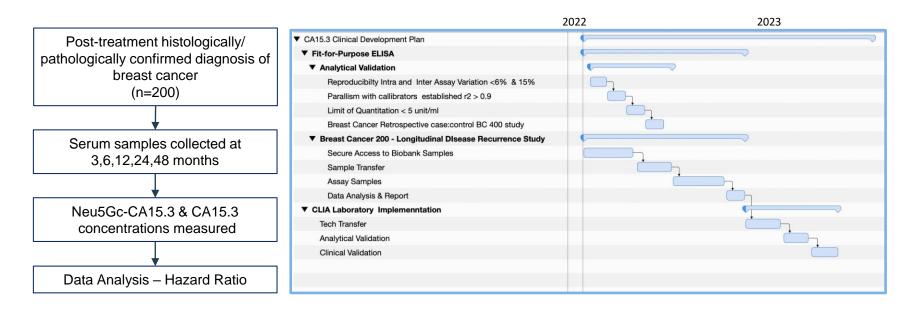
Proceedingly Collected Petrocesciticaly Analysed Longitudinal Project Concer Study

Prospectively Collected Retrospectively Analysed Longitudinal Breast Cancer Study		
Study Design	Prospective Longitudinal Clinical Cohort Study	
Objective	CA15.3 is still a widely used test for monitoring breast cancer, although recent reports discourage its routine use because of low sensitivity. This is a prospective study to evaluate the efficacy of Neu5Gc-CA15.3 (a cancer-specific glycovariant) in monitoring breast cancer recurrence.	
Description	200 patients with a histologically/pathologically confirmed diagnosis of breast cancer and recurrence or metastasis after surgery. Peripheral venous blood collected every 3 to 6 months. Serum concentrations of Neu5Gc-CA15.3 (INOVIQ) and CA15.3 (Elecsys <sup>®</sup> CA 125 II (Roche)) will be measured at different follow-up time points.	
Clinical Samples	Previously bio-banked samples	
Primary Outcome Measure	Neu5G-CA15.3 not inferior to CA15.3 (as assessed by Cox proportional hazards models with a time-varying indicator)	
Secondary Outcome Measure	Sensitivity of Neu5Gc-CA15.3 > CA15.3	





#### Intended use: A blood test to aid in monitoring breast cancer recurrence





### Cancer Risk Assessment | SubB2M-based SPR test



- POC data in case-control studies showed the SubB2M-based SPR test detected:
  - Ovarian Cancer at 100% sensitivity and 100% specificity across all stages (n = 69)  $^{1,2}$
  - Breast Cancer at 95% sensitivity and 100% specificity across all stages (n = 118)<sup>1,2,3</sup>
- Commenced transfer, development and evaluation of SubB2M-based SPR test on Nicoya's next-gen Alto digital SPR instrument<sup>4</sup>
- In development for cancer risk assessment in conjunction with approved screening tests
- Potential for further development as a multi-cancer detection test



#### SENSITIVITY BY STAGE n=118 (96 cancers : 22 controls) n=69 (47 cancers : 22 controls) 100% 100% 10.5 GPU 10.5 GPU 10.5 GPU 10.5 GPU Stage I Stage IV Stage I Stage II Stage III Stage IV Stage II Stage III

SENSITIVITY BY STAGE<sup>1</sup>

**Breast Cancer data** 

POC = Proof of Concept; SPR = Surface Plasmon Resonance; OC = Ovarian Cancer; CRO = Contract Research Organisation

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1. Shewell et al. N-alycolylneuraminic acid serum biomarker levels are elevated 3. Collaborative Research Agreement with the Institute for Glycomics at Griffith in breast cancer patients at all stages of disease. BMC Cancer (2022) 22:334: University; 4. ResearchDx engaged under Master Services Agreement (ASX: https://rdcu.be/cJ21m; ; 5/4/22) 2. Samples provided by Victorian Cancer Biobank 4. Contract Research Agreement with Nicova Lifesciences Inc (ASX: 13/10/22

### 

**Ovarian Cancer data** 

# Diagnostics | Commercialisation strategy



#### Stepped approach to commercialisation:

- Market entry: Initially US, then expand to EU, AU and others
- Regulatory: Initially LDT, then IVD route
- Indication for use: Initially monitoring (SubB2M), or triage / high-risk screening (Exosomal OC), before general screening
- Clinical: Evidence of clinical performance in intended use population
- Partnering: CLIA-accredited high complexity Lab for commercialization of tests as LDTs

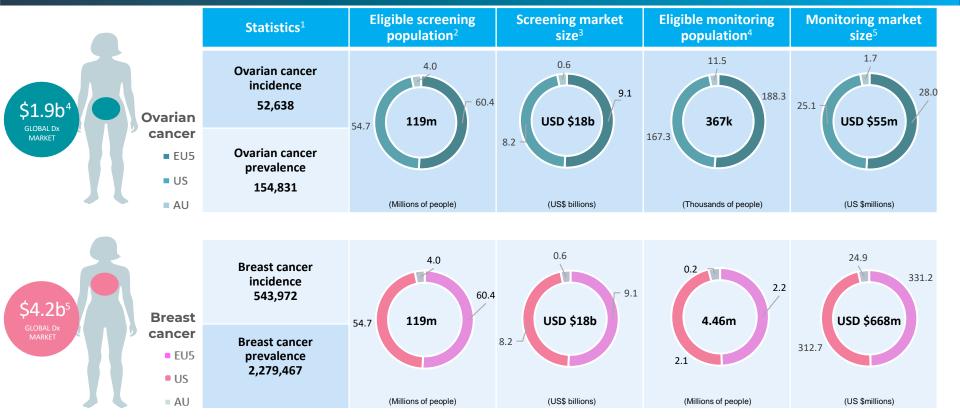
Laboratory Developed Test (LDT)	In Vitro Diagnostic (IVD)
CLIA	FDA 510k clearance / PMA approval
Development & validation in a single laboratory	Larger-scale clinical studies required
Laboratory partner	Distribution partner
Diagnostic service provided to laboratories and clinicians	Kits for sale to hospitals, clinical laboratories and doctors' offices
Faster and lower cost, delivers early revenue & establishes market acceptance	Slower and higher cost, delivers wider clinical adoption & revenue growth



## Market potential | Screening and monitoring

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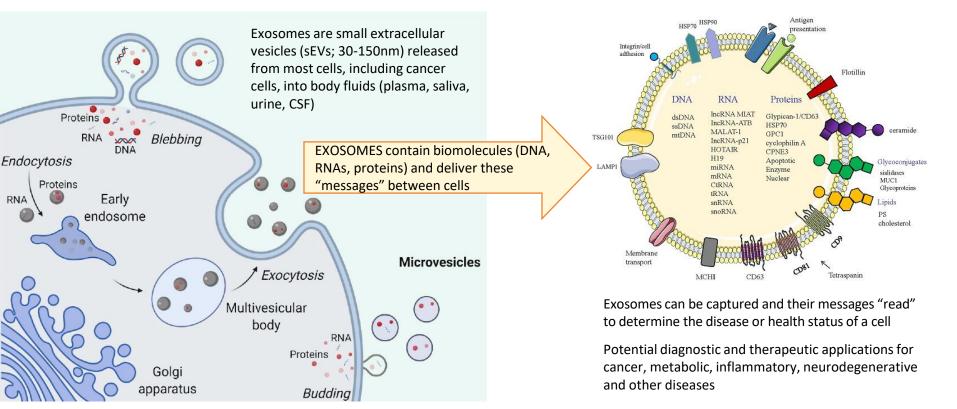




1 Source: <a href="https://goo.iarc.ft/loday/home.covering">https://goo.iarc.ft/loday/home.covering</a> US, EU5 and AU . 2. Females 50-79yrs covering US, EU5 and AU (Source: <a href="https://www.gooulationpyramid.net">https://www.gooulationpyramid.net</a>). Assumed cancer screening test price US\$150 per test 4 Monitoring population based on 4x prevalence plus 1x incidence 5. Assumed cancer screening test price at US\$150 per test 4 Monitoring release/2019/08/07/1894530/en/Ovarian-Cancer-Diagnostics-Market-Size-Worth-US-1-8 Br-by-2026.html; 5 https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market</a>

## Exosomes | Diagnostic and therapeutic potential





## **EXO-NET I Exosome isolation tools**

- **EXO-NET pan-exosome capture** is a 'research use only' (RUO) product for isolation of exosomes from body fluids
- Meets and unmet need for rapid, efficient and scalable isolation of exosomes
- **Suitable** for biomarker discovery, research & development phases of future exosome-based diagnostics & therapeutics
- Expanding EXO-NET pipeline including TEXO-NET for cancer EVs, NEURO-NET for bdEVs<sup>1</sup>, automated and HTP EXO-NET solutions compatible with routine pathology workflows
- **Collaborating** with KOLs to validate EXO-NET for cancer, inflammatory, metabolic and neurodegenerative diseases
- Direct sales of EXO-NET products to Universities & Research Institutes
- Partnered with Percorso Life Sciences for contract sales team & logistics services in the US to **accelerate commercial roll-out**<sup>4</sup>
- Initial sales campaign to >1000 researchers is expected to deliver results in 1H CY2023





# EXO-NET | Speed, purity and yield advantages



FAST	Easy and convenient workflow with EV capture in 15 minutes
SAMPLE VERSATILITY	Optimal solution for very low volume and rare samples from plasma, urine, saliva
HIGH YIELD	High yield and capture of EVs from various biofluids
PURITY	Reduced co-isolation of contaminants and high enrichment of EV RNA and protein markers
DOWNSTREAM COMPATIBILITY	Compatible for use with most downstream applications (qPCR, Mass Spec, ELISA)
CUTOMIZABLE	Customizable to isolate specific EV subpopulations for use in target disease indications
SCALABLE	Suitable for automation and high-throughput screening



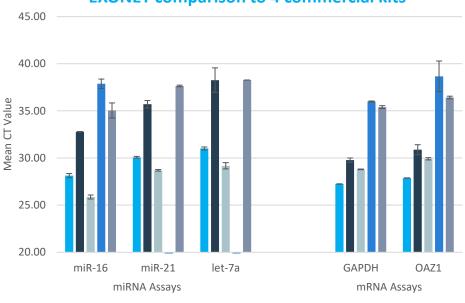


**EXONET outperforms or is equivalent to 4 commercial EV isolation kits** for recovery of EV micro RNA (miRNA) and messenger (mRNA) as indicated by lower CT values.<sup>1,2</sup>

"The use of a scalable exosome isolation tool such as INOVIQ's EXO-NET product is critical to enable the commercialisation of routine exosome-based tests that can be used in pathology laboratories worldwide."

Associate Professor Carlos Salomon Gallo Head of Exosome Biology Laboratory, University of Queensland

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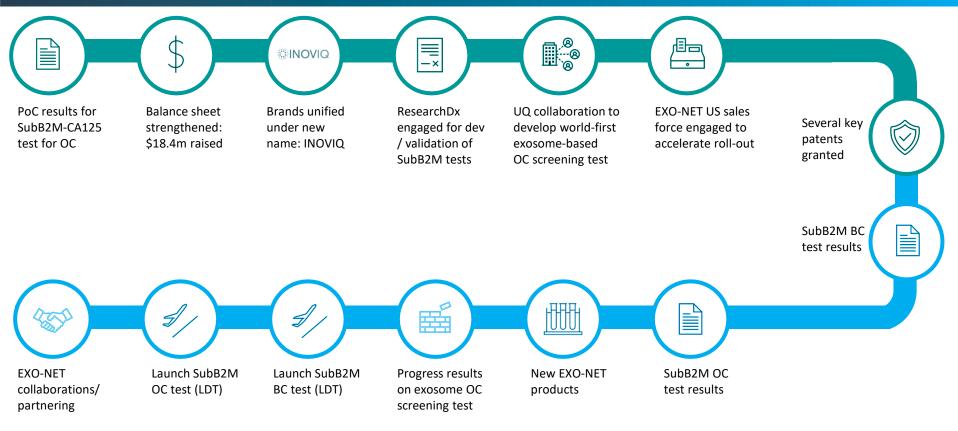
EXO-NET A B C D

#### **EXONET comparison to 4 commercial kits**

1. INOVIQ data 2 Evaluation by leading Australian Research Institute

## Key achievements of 2022 and catalysts for 2023







# Contacts

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### **Board and Management**



#### DR GEOFF CUMMING PhD Non-Executive Chairman

Healthcare and biotechnology director with extensive diagnostics industry experience.

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

Currently NED AnteoTech Ltd.

#### MAX JOHNSTON Non-Executive Director

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

Previously President and CEO of Johnson & Johnson Pacific, NED of PolyNovo Ltd and CannPal Animal Therapeutics Ltd, and Chairman of AusCann Ltd.

Currently NED of Medical Developments International Ltd & Tissue Repair Ltd, and interim CEO of PolyNovo 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 Polynovo Ltd and Medical Developments International Ltd.

Currently NED RMA Global Ltd.



#### Prof ALLAN CRIPPS AO PhD Non-Executive Director

Distinguished academic, clinical scientist and health services leader, having made significant contributions in immunology, diagnostics and health services.

Previously Pro Vice Chancellor (Health) at Griffith University where he was responsible for the establishment of the Health Faculty including the School of Medicine.

Currently Professor Emeritus at Griffith University and NED of Neurotech International Ltd.

#### DR LEEARNE HINCH Chief Executive Officer

Experienced biotechnology CEO with expertise in corporate development, capital

raising, product development, commercialisation and licensing. Past leadership and consulting roles in ASXlisted biotechnology, multinational and

private companies across diagnostics, devices, therapeutics and animal health including Eustralis Pharmaceuticals, HealthLinx, OBJ, Holista Colltech, Virbac & Mars.

#### DR GREG RICE PhD Chief Scientific Officer

Internationally recognised scientist with over 30 years' experience and a successful track record in oncology research, biomarker trials and diagnostics commercialisation.

Previous leadership roles in academia and industry including UQ, Baker Heart Institute, UoM, Monash & HealthLinx.



#### MARK EDWARDS CFO & Company Secretary

Highly 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.



#### Dr ROCCO IANNELLO Business Development and Licensing Director

Senior business development professional and research scientist with experience in IP commercialisation, business development and licensing across medical devices & pharmaceuticals.

Strong Australian and international networks across government, academia, industry and venture capital. Previous senior roles at Monash, Ward Medication Management & Gordagen Pharmaceuticals.

