

## **Investor Presentation**

## Bell Potter Healthcare Conference 2023



ASX: IIQ | 16 November 2023

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## Company snapshot





Financial information (ASX:IIQ)	
Ordinary shares <sup>2</sup>	92,018,702
Listed options <sup>2</sup>	2,611,349
52-week H/L <sup>2</sup>	A\$0.990-0.460
Share price <sup>2</sup>	A\$0.60
Market capitalisation <sup>2</sup>	A\$55.2m
Cash at bank <sup>1</sup>	A\$6.3m
Major shareholders (as at 10 November 2023)	
Merchant Funds Mgt Pty Ltd	14.2%
Moggs Creek/Lawn Views Pty Ltd	5.3%
Share price performance	
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## Board and Management | Healthcare, corporate & commercial experience





#### DR GEOFF CUMMING 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, Chairman of AusCann Ltd, NED of PolyNovo Ltd, Medical Developments International Ltd, Tissue Repair Ltd and CannPal Animal Therapeutics Ltd.

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#### 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.



#### DR LEEARNE HINCH

#### Chief Executive Officer

Biotechnology CEO with a successful track record 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 and Mars.



## DR GREG RICE

Internationally recognized, 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 Uni Queensland Centre for Clinical Research, Baker Heart Institute, University of Melbourne, Monash University and 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.





# Focused on advancing the development and commercialisation of our SubB2M and EXO-NET platforms

- Clinically validated SubB2M technology and commenced BC monitoring study to enable partnering for LDT commercialisation
- Developed, validated and commissioned high-throughput EXO-NET exosome isolation system to enable a complete exosome concept-to-clinic diagnostics solution
- Secured commercial partners for EXO-NET with Promega and ResearchDx to drive future revenues
- Progressed pipeline of EXO-NET research tools, SubB2M tests and exosome diagnostics
- Initiated discussions for potential co-development of exosome diagnostics (using EXO-NET)
- Expanded Board with the appointment of experienced director, David Williams, as Chairman elect<sup>1</sup>











#### **STRATEGIC FOCUS**

Leading exosome solutions and precision diagnostics company focused on improving patient outcomes for cancer



## Products and pipeline | multi-stage research tools and cancer diagnostics



- Exosome research tools for exosome isolation, biomarker discovery and diagnostics development
- Blood tests for earlier and more accurate detection of breast, ovarian and other cancers

	PRODUCT	INDICATION	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL DEVELOPMENT	MARKET	
	hTERT <sup>1</sup>	Bladder Cancer	Adjunct to cytology			IVD-Clas	s 1 USA	
ŏ	SubB2M-BC	Breast Cancer	Monitoring			LDT		
B2N	SubB2M-OC	Ovarian Cancer	Monitoring		LDT			
Subl	SubB2M-SPR	Multi-cancer	Pre-screening	LDT				
ă	EXO-OC <sup>2</sup>	Ovarian Cancer	Screening		LDT			
ols/I	EXO-NET RUO	pan-EV capture	Research tool				RUO	
0 tõ	TEXO-NET RUO	tumour derived-EV capture	Research tool	RUO				
Ň	NEURO-NET RUO	brain derived-EV capture	Research tool	RUO				

NOTE: Development pipeline is indicative only, subject to review.

\*EV = Extracellular Vesicles ; ICC = Immunocytochemistry; IVD = In Vitro Diagnostic; LDT = Laboratory-Developed Test; RUO = Research Use Only 1. Adjunct to urine cytology to assist the detection of bladder cancer; 2 Umbrella Research & Option Agreement with the University of Queensland



## SubB2M technology platform



#### Scientific rationale

- Cancer cells have a distinct feature of adding different sugar molecules to the proteins they produce, which sets them apart from normal cells
- **Neu5Gc** is a sugar molecule commonly found in cancer cells
- SubB2M is an engineered protein that preferentially binds to Neu5Gc
- SubB2M is a promising multicancer probe
- Incorporating SubB2M into existing cancer biomarker tests, may improve sensitivity and specificity for detecting various types of cancer







#### Clinical-stage and progressing towards partner-ready by Dec 2023 to enable LDT commercialisation

Breast cancer	<ul> <li>#1 cancer in women</li> <li>2 3m new cases of breast cancer worldwide na<sup>1</sup></li> </ul>	Development stage	
• 7.8m survivors (5-year) <sup>1</sup>		Feasibility Completed	
Unmet medical need	<ul> <li>Earlier and more accurate detection and monitoring tests required for breast cancer</li> <li>US\$4.2b global diagnostics market<sup>2</sup></li> </ul>	Assay development Completed	
Disruptive technology	<ul> <li>SubB2M is an engineered protein that specifically binds the pan-cancer biomarker Neu5Gc<sup>3</sup></li> <li>Improved immunoassay for detection of Neu5Gc decorated CA15-3</li> <li>Increased sensitivity and specificity to detect cancer over existing assays</li> </ul>	Analytical validation (n=94) Completed	
Intended use	• Aid in <b>monitoring</b> breast cancer treatment response and disease recurrence in women previously diagnosed with disease	(n=483) Monitoring study H2 CY23	
Go-to-market strategy	• LDT then IVD (510k/PMA process) • Partner with a CLIA-accredited laboratory	LDT partner ready O Dec 2023	

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. https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market; 3 NeuSGv = the sialic acid, N-glycolylneuraminic acid

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#### Clinical validation study | completed

Retrospective, case-control, clinical validation study in 483-samples • demonstrated SubB2M/CA15-3 test detected breast cancer across all stages with high accuracy (AUC 0.93, 81% sensitivity and 93% specificity) and outperformed a leading approved CA15-3 test<sup>1</sup>

#### **Breast Cancer monitoring study | commenced**

- 2-phase monitoring study in over 200-samples to evaluate ٠ performance of SubB2M/CA15-3 test as an aid for monitoring treatment response and/or disease recurrence compared to approved CA15-3 test
- Data expected Dec-23



SubB2M/CA15-3 and compar <b>ator</b> CA15-3 test		
performance summary		

Breast Cancer All Stages	SubB2M	Comparator
AUC	0.93	0.70
sensitivity	81%	37%
specificity	93%	88%
false negative rate	19%	63%
false positive rate	7%	12%
positive predictive value	92%	75%
negative predictive value	83%	58%
overall accuracy	87%	63%

#### Test Sensitivity by stage @95% Specificity





Study 1: To determine whether SubB2M/CA15-3 is equally expressing in women with different subtypes of breast cancer





### Study 2: To determine the accuracy of SubB2M/CA15-3 to identify breast cancer recurrence





### Progressing towards clinical validation

Ovarian cancer	• #8 cancer in women & <b>deadliest gynaecological cancer</b>	Development stage		
• 823k survivors (5-year) <sup>1</sup>		Feasibility • Completed		
Unmet medical need	<ul> <li>Earlier and more accurate detection and monitoring tests required for ovarian cancer</li> <li>US\$1.8b global diagnostics market<sup>2</sup></li> </ul>	Assay development H2 CY23		
Disruptive technology	<ul> <li>SubB2M is an engineered protein that specifically binds the pan-cancer biomarker Neu5Gc</li> <li>Improved immunoassay for detection of Neu5Gc decorated CA125</li> <li>Increased sensitivity and specificity to detect cancer over existing assays</li> </ul>	Analytical validation H2 CY23		
Intended use	<ul> <li>Aid in monitoring ovarian cancer treatment response and disease recurrence in women previously diagnosed with disease</li> </ul>	Monitoring study H1 CY24		
Go-to-market strategy	<ul> <li>LDT then IVD (510k/PMA process)</li> <li>Partner with a CLIA-accredited laboratory</li> </ul>	LDT partner ready O Jun 2024		





SubB2M/CA15-3 test is expected to be partner-ready in December 2023 for commercialisation as a Laboratory Developed Test

Build analytical and clinical validation data package

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Commercialise first as an LDT in the USA with a lab partner to generate early revenue Complete IVD medical device development and regulatory approval via 510k / PMA pathway

Secure IVD partners and approvals in major markets to expand geographic reach and grow revenue



## Market potential | Screening and monitoring tests

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1 Source: <a href="https://gco.iarc.fr/today/home">https://gco.iarc.fr/today/home</a> covering US, EU5 and AU; 2. Females 50-79yrs covering US, EU5 and AU (Source: <a href="https://www.populationpyramid.net">https://www.populationpyramid.net</a> ).; 3. Monitoring population based on 4x incidence plus 1x prevalence; 4. <a href="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">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">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</a> 5. <a href="https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market">https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market</a>



## Exosomes | Diagnostic and therapeutic potential





- Exosomes are released by cells and perform key roles in intercellular communication, immune regulation and pathogenesis
- Diseases elicit changes in the release of exosomes and their molecular cargo (DNA, RNA and proteins)
- Exosomes can be isolated from biofluids (including blood, urine and saliva) and their messages "read" to diagnose the **health** or **disease status** of the parent cell
- Exosome **diagnostics and therapeutics** are being developed for oncology, neurology, cardiology, immunology, inflammatory and other diseases
- Commercial potential limited by **time-consuming and inefficient exosome isolation** methods that are not suitable for commercial applications
- INOVIQ has developed **fast, efficient and scalable** exosome isolation technology

US\$661m Exosome research market<sup>1</sup> US\$8.7b Exosome diagnostic & therapeutic market<sup>2</sup>





Immunoaffinity magnetic bead-based capture system for isolation and analysis of exosomes



## EXO-NET research tools and services | commercially available





#### EXO-NET PAN-EXOSOME CAPTURE

EXO-NET is a research tool for fast, efficient & scalable exosome isolation from plasma, serum, urine, saliva and cell-conditioned media<sup>1,2, 3</sup>



#### CUSTOMISED EXO-NET TOOLS

Design custom EXO-NET tools using ligands for specific EV populations



#### EXOSOME ISOLATION

EV isolation using EXO-NET powered, fully-automated, high-throughput platform<sup>1</sup>



#### BIOMARKER DISCOVERY

Biomarker discovery to identify, evaluate and validate EVbased RNA and Protein biomarkers



#### DIAGNOSTICS DEVELOPMENT

EV-based clinical diagnostics, clinical trial assays and companion diagnostics





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### SubB2M and EXO-NET programs moving towards key inflection points

H2 CY 2023	H1 CY 2024
EXO-NET co-marketing agreement with Promega	Commercial progress SubB2M/CA15-3 LDT
Results of EXO-OC equivalence study in plasma and serum (n=250)	Results SubB2M/CA125 OC clinical validation studies
Results SubB2M SPR feasibility study	NEURO-NET data
Results SubB2M/CA125 OC analytical validation study	New EXO-NET collaborations / partnering
Results of SubB2M/CA15-3 BC monitoring study	Progress EXO-OC test collaboration and clinical data
Progress SubB2M partnering	
TEXO-NET data @ ANZSEV23 meeting	



## Summary | Next generation diagnostic solutions advancing towards key milestones







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