

# **CEO** Presentation

Annual General Meeting 2023



ASX: IIQ | 29 November 2023

### Disclaimer



This presentation has been prepared by INOVIQ Limited ("INOVIQ" or the "Company") based on information available to it as at the date of this presentation. This presentation contains general and background information about the Company's activities current as at the date of the presentation and should not be considered to be comprehensive or to comprise all the information that an investor should consider when making an investment decision and does not contain all information about the Company's assets and liabilities, financial position and performance, profits and losses, prospects, and the rights and liabilities attaching to the Company's securities necessary to make an investment decision. The information in this presentation should be read in conjunction with the Company's other periodic and continuous disdosure announcements lodged with the Australian Securities Exchange (ASX), available at www.asx.com.au. The information in this presentation is based on the Company's own information and estimates and has not been independently verified. The Company is not responsible for providing updated information and assumes no responsibility to do so. Any investment in the Company should be considered speculative and there is no guarantee that they will make a return on capital invested, that dividends would be paid, or that there will be an increase in the value of the investment in the future.

This Presentation may contain certain "forward-looking statements" that are based on management's beliefs, assumptions and expectations and on information currently available to management. The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Any indications of, and guidance on, future operating performance, eamings, financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this Presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions.

Actual results, performance or a chievements could be significantly different from those expressed in, or implied by, these forward-looking statements. No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including INOVIQ or any of its advisers). In particular, no representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward-looking statements in this Presentation will actually occur. Actual operations, results, performance, targets or a chievement may vary materially from any projections and forward-looking statements and the assumptions on which those statements are based.

Nothing contained in this Presentation constitutes investment, legal, tax or other advice. This Presentation does not purport to be all indusive or to contain all information which its recipients may require in order to make an informed assessment of the Company's prospects.

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.

# 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\$0.625
Market capitalisation <sup>2</sup>	A\$57.5m
Cash at bank <sup>1</sup>	A\$6.3m
Major shareholders (as at 24 November 2023)	
Merchant Funds Mgt Pty Ltd	14.2%
Moggs Creek/Lawn Views Pty Ltd	5.3%
Share price performance	
1.90	
50	m
50 40	

# Key achievements FY2023 to date







#### **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 ٠
- Blood tests for earlier and more accurate detection of breast, ovarian and other cancers ٠

	PRODUCT	INDICATION	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL DEVELOPMENT	MARKET
	hTERT <sup>1</sup>	Bladder Cancer	Adjunct to cytology			IVD-Clas	ss 1 USA
č	SubB2M-BC	Breast Cancer	Monitoring			LDT	
	SubB2M-OC	Ova ri a n Ca ncer	Monitoring		LDT		
Inno	SubB2M-SPR	Multi-cancer	Pre-s creening	LDT			
Ś	EXO-OC <sup>2</sup>	Ova ri a n Ca ncer	Screening		LDT		
	EXO-NET RUO	pan-EV capture	Research tool				RUO
	TEXO-NET RUO	tumour de rived-EV capture	Research tool	RUO			
S	NEURO-NET RUO	brain derived-EV capture	Research tool	RUO			

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



# Exosomes | diagnostic and therapeutic potential





Image source: Meletios Verros/Shutterstock.com; 1. MarketandMarkets. Exosome Research Market (2021-2026). 2020; 2. Exosomes Market: Global Industry Analysis and Forecast (2023-2029) [maximizemarketresearch.com]

- 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>



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 to identify, evaluate and validate EVbased RNA and Protein biomarkers

Promega



#### DIAGNOSTICS DEVELOPMENT

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





# SubB2M technology platform

#### Scientific rationale

- Aberrant glycosylation (adding sugars) is a hallmark of cancer
- **Neu5Gc** is a sugar molecule commonly found in cancer cells, but not healthy normal cells
- **SubB2M** is an engineered protein that preferentially binds to Neu5Gc, making it a promising **multicancer probe**
- Incorporating SubB2M into existing cancer biomarker tests, may improve sensitivity and specificity for detecting various cancers including breast, ovarian, prostate, pancreatic, lung & others





### 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 pa<sup>1</sup></li> <li>7.8m survivors (5-year)<sup>1</sup></li> </ul>	Development stage		
		Feasibility Completed		
Unmet medical need	<ul> <li>Non-invasive, earlier and more accurate tests required for monitoring breast cancer recurrence</li> <li>10-40% breast cancers recur within 5 years</li> <li>US\$4.2b global breast cancer 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 Clinical validation Completed		
Intended use	<ul> <li>Aid in monitoring breast cancer treatment response and disease recurrence in women previously diagnosed with disease</li> </ul>	(n=483) Monitoring study H2 CY23		
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 Dec 2023		

12
510k = FDA clearance for Class II device; CLIA = Clinical Laboratory Improvement Amendments (high-complexity tests); IVD = In Vitro Diagnostic; LDT = Laboratory Developed Test;
1. <a href="https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market;">https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market;</a>; ND = In Vitro Diagnostic; LDT = Laboratory Developed Test;
1. <a href="https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market;">https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market;</a>; Neu Sov = the siolic acid, N-glycolylneuraminic acid



#### 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 • 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 comparator CA15-3 te	st
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



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



Study 1: To determine whether NeuCA15-3 is equally expressed 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	<ul> <li>#8 cancer in women &amp; deadliest gynaecological cancer</li> <li>314k new cases of ovarian cancer worldwide pa<sup>1</sup></li> <li>823k survivors (5-year)<sup>1</sup></li> </ul>	Development stage		
	• Non-invasive, earlier and more accurate tests required for monitoring	Feasibility Completed		
Unmet medical need	<ul> <li>ovarian cancer recurrence</li> <li>50% ovarian cancers recur within 5 years</li> <li>US\$1.8b global ovarian cancer 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	• Aid in <b>monitoring</b> ovarian cancer treatment response and disease recurrence in women previously diagnosed with disease	Clinical validation H1 CY24 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		





#### Developing an accurate and reliable test for early detection of ovarian cancer

Ovarian cancer	<ul> <li>#8 cancer in women &amp; deadliest gynaecological cancer</li> <li>314k new cases of ovarian cancer worldwide pa<sup>4</sup></li> <li>823k survivors (5-year)<sup>4</sup></li> </ul>	Development stage		
Unmet medical need	<ul> <li>No approved test for early detection of ovarian cancer in asymptomatic, average-risk women</li> <li>U\$\$1.8b global ovarian cancer diagnostics market<sup>5</sup></li> </ul>	Feasibility Completed Assay development Ongoing		
Disruptive technology	<ul> <li>EXO-NET enables isolation of exosomes for earlier and more accurate cancer detection</li> <li>EXO-OC test in development as world-first EXO-NET enabled exosomal In Vitro Diagnostic Multivariate Index Assay (IVD-MIA)</li> </ul>	Plasma-serum equivalence Completed Case-control clinical study Commence H1 CY24		
Intended use	• Screening to detect ovarian cancer in asymptomatic, high-risk women aged 35 years and over	Clinical validation		
Go-to-market strategy	• LDT then IVD-MIA (PMA process)	LDT market ready		

PMA = Pre-Market Approval; 1. Research and Option Agreement with The University of Queensland (UQ) (ASX: 1/4/22); 2. Early research supported by an Ovarian Cancer Research Foundation (OCRF) grant; 3. Current research supported by a \$2.7m Medical Research Future Fund (MRFF); 4. Cancer Today (iarc.fr.); 5. Ovarian Cancer Diagnostics Market Size Worth US\$ 1.8 Bn by (globenewswire.com)



17



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

**Complete IVD Secure IVD partners Commercialise first Build analytical** medical device and approvals as an LDT in the USA and clinical development and in major markets to with a lab partner to validation data regulatory approval expand geographic generate via 510k / PMA package reach and grow early revenue pathway revenue



# SubB2M tests | workflow



# **Collection Centre**



Routine venipuncture

transit @ 4<sup>0</sup>C

# Serum collected

# **Routine Pathology Laboratory**



Standard Autoanalyzer

SubB2M tests are fully compatible with existing pathology laboratory workflow



Sample Report

# Market potential | screening and monitoring tests

19





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.gcandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market">https://www.gcandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market</a>





## 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
SEXO-NET services license agreement with ResearchDx	• NEURO-NET data
🗹 TEXO-NET data @ ANZSEV23 meeting	New EXO-NET collaborations/partnering
🔗 HT EXO-NET data @ AMP23 meeting	Progress EXO-OC test collaboration and clinical data
Results SubB2M SPR feasibility study	
Results SubB2M/CA125 OC analytical validation study	
Results of SubB2M/CA15-3 BC monitoring study	



# Summary | Next generation diagnostic solutions advancing towards key milestones







# Contacts



#### INOVIQ Ltd

23 Normanby Road Notting Hill VIC 3168 Australia

P +61 3 9548 7586 E <u>info@inoviq.com</u> W <u>www.inoviq.com</u>

Dr Leearne Hinch | CEO E <u>lhinch@inoviq.com</u> M +61 400414416



