Accelerating momentum in 2023

ASX: IIQ | 1 August 2023

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About INOVIQ Ltd

INOVIQ's mission is to develop next-generation precision diagnostics and exosome solutions that transform the diagnosis and treatment of cancer and other diseases to improve patient outcomes and save lives

Precision focus

Precision diagnostic and exosome solutions to improve patients' lives

Disruptive technology

Proprietary technology platforms driving future products for cancer and other diseases

Deep pipeline

Multi-stage pipeline including SubB2M diagnostics, exosome research tools and exosome diagnostics

Compelling data

SubB2M/CA15-3 test shows 81% sensitivity & 93% specificity for BC detection[1], and EXO-NET captures >50% target exosomes[2]

Commercial products

Commercial exosome isolation tools targeting US$661m exosome research market[3], and bladder cancer detection test

Partnering for growth

Partnering with KOLs and industry to deliver clinical and commercial outcomes, with SubB2M/CA15-3 test expected market ready for LDT partner Dec-23

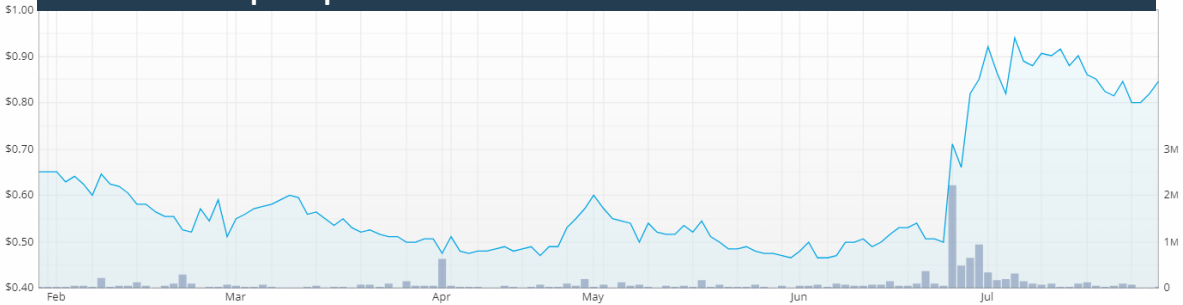
**LDT = Laboratory-Developed Test; 1. ASX 27 June 2023; 2. ASX: 19 May 2023 for manual EV isolation; 3.* MarketandMarkets. Exosome Research Market. 2020

Company snapshot

INOVIQ snapshot

- **Founded 2016** as a single-asset diagnostics company focused on earlier cancer detection
- Multiple **acquisitions and in-licensing** to expand technology portfolio
- Headquartered in **Melbourne, Australia** with regional office in US
- 17 **employees** including 9 R&D staff with 7 PhDs
- **Expertise** in research, development, clinical testing and commercialisation of cancer diagnostics and exosome solutions
- **Facilities** include cGMP manufacturing, ISO17025 laboratories and cell culture
- **Multi-product pipeline** for exosome isolation and diagnostics
- **Partnering** with leading KOLs and Industry to deliver better healthcare outcomes

6-month share price performance



Financial information (ASX:IIQ)

Ordinary shares[2]	92,018,702
Listed options[2]	5,909,965
52-week H/L	A$0.990-0.460
Share price[2]	A$0.845
Market capitalisation[2]	A$77.8m
Cash at bank[1]	A$7.8m

Major shareholders (as at 28 July 2023)

Merchant Funds Mgt Pty Ltd	14.2%
Moggs Creek/Lawn Views Pty Ltd	5.3%
TOP 20	**35.6%**

1. Cash at 30 Jun 2023 (ASX: Appendix 4C, 28 July 2023); 2. As at 28 Jul 2023.

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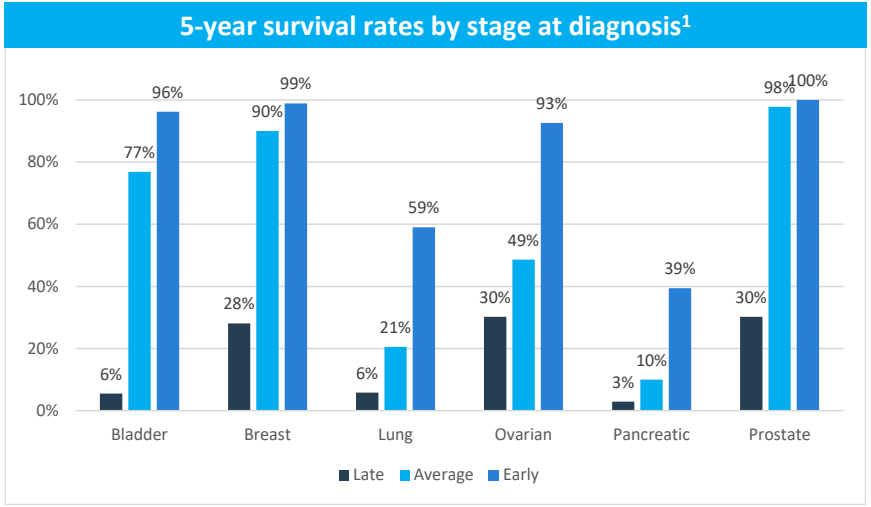
Unmet need for early cancer detection

Unmet need

- Unmet needs for non-invasive, accurate and reliable diagnostic tests for earlier cancer detection and monitoring
- Earlier detection improves treatment options, patient outcomes & survival [1]

INOVIQ solutions

- ✓ Screening tests for earlier detection of cancer
- ✓ Predictive tests to guide therapeutic selection
- ✓ Monitoring tests for treatment response and/or disease recurrence



1. SEER 18 2010-2016

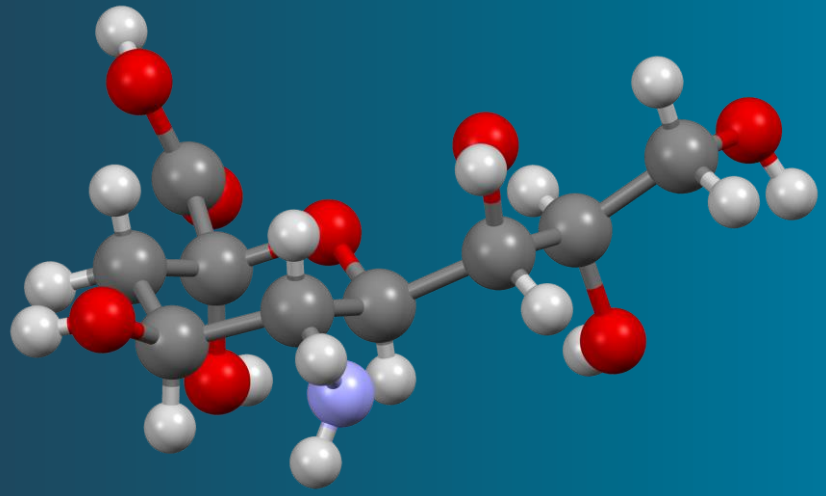
Products and pipeline | Expanding EXO-NET tools and diagnostics portfolio

	PRODUCT	INDICATION	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL DEVELOPMENT	MARKET
	hTERT[1]	Bladder Cancer	Adjunct to cytology	IVD-Class 1 USA			
SubB2M Dx	**SubB2M-BC**	Breast Cancer	Monitoring	LDT			Dec-23
SubB2M Dx	**SubB2M-OC**	Ovarian Cancer	Monitoring	LDT			Jun-24
SubB2M Dx	**SubB2M-SPR**	Multi-cancer	Pre-screening	LDT			
EXO tools/Dx	**EXO-OC**[2]	Ovarian Cancer	Screening	LDT			
EXO tools/Dx	**EXO-NET RUO**	pan-EV capture	Research tool	RUO			
EXO tools/Dx	**TEXO-NET RUO**	tumour derived-EV capture	Research tool	RUO			
EXO tools/Dx	**NEURO-NET RUO**	brain derived-EV capture	Research tool	RUO			

**RUO = Research Use Only; ICC = Immunocytochemistry; LDT = Laboratory-Developed Test; bd-Ev = brain-derived Extracellular Vesicles; td-EV = tumour-derived Extracellular Vesicles; HT = high-throughput*

1. Adjunct to urine cytology to assist the detection of bladder cancer; 2 Umbrella Research & Option Agreement with the University of Queensland

SubB2M diagnostics



Improved SubB2M-based cancer diagnostic tests for cancer detection and monitoring

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INOVIQ INVESTOR BRIEFING INVITATION

Melbourne, Australia, 27 June 2023: INOVIQ Limited (ASX:IIQ) (**INOVIQ** or the **Company**), is pleased to invite investors to attend a special online briefing to discuss the Company's announcement (released earlier today) of outstanding clinical data for its SubB2M/CA15-3 test for breast cancer detection.

The briefing will be presented by Chief Executive Officer, Dr Leanne Hinch together with Chief Scientific Officer, Dr Greg Rice.

Session details:

Date: Thursday, 29 June, 2023

Time: 11:00am Australian Eastern Standard Time (Melbourne Time)

Format: Presentation, followed by a Q+A session

Register: Participants can register ahead of time via the following link https://us02web.zoom.us/webinar/register/WN_etcvaaBmT-Kh2NDrtdCSWw#/registration

After registering, investors will receive a confirmation email with details on how to join the session.

- ENDS -

Authorised by the Company Secretary, Mark Edwards.

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ABOUT INOVIQ LTD

INOVIQ Ltd (ASX:IIQ) (**INOVIQ**) is developing and commercialising next-generation exosome solutions 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 www.inoviq.com.

ABOUT SUBB2M PLATFORM

SubB2M is an engineered protein that preferentially binds to the pan-cancer biomarker Neu5Gc, found in multiple human cancers. INOVIQ is developing SubB2M blood tests for multiple uses, including monitoring breast and ovarian cancers, and for a general health panel.

SubB2M may enhance the performance of existing tumour marker tests by binding to multiple Neu5Gc sites on the biomarker that amplify the signal and improve sensitivity, and by increasing the cancer specificity to reduce false positives.

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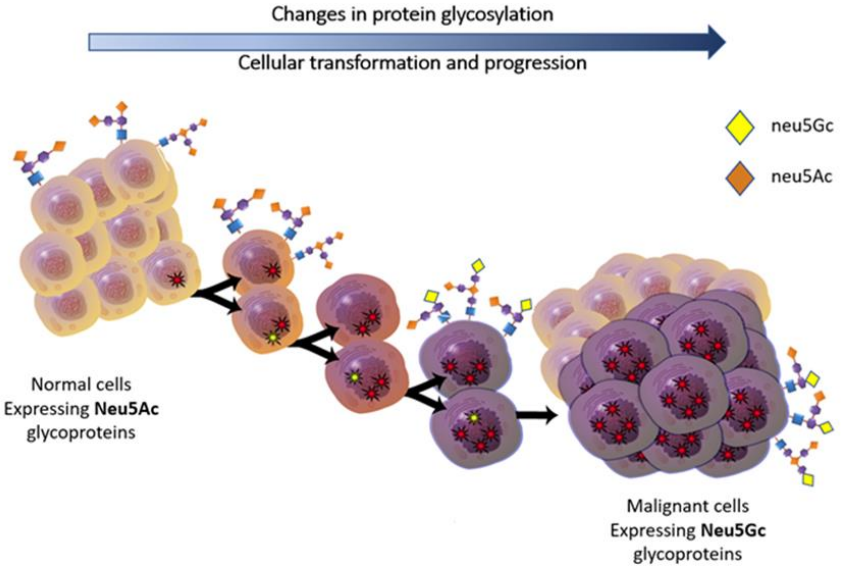
SubB2M technology platform

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
- One such sugar molecule commonly found in cancer cells is Neu5Gc
- SubB2M preferentially binds to Neu5Gc
- SubB2M is a promising multicancer probe
- Incorporating SubB2M into existing cancer diagnostic tests, may improve their sensitivity and specificity in detecting various types of cancer



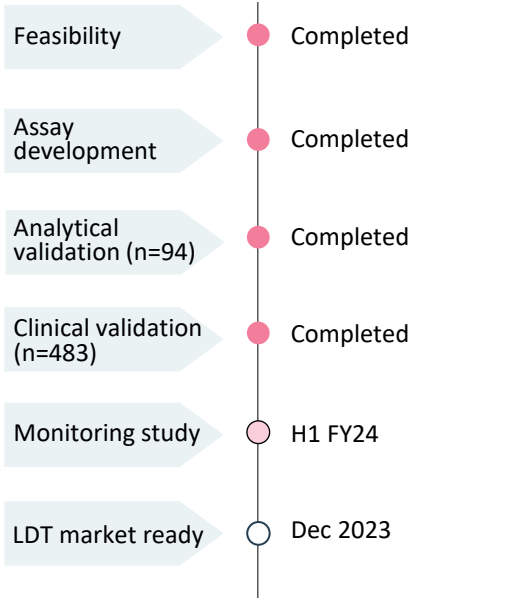
Neu5Gc = the sialic acid, N-glycolylneuraminic acid

SubB2M/CA15-3 Breast Cancer test | improved BC monitoring

Clinical-stage and progressing towards market-ready for LDT partnering by Dec 2023

Breast cancer	• #1 cancer in women • 2.3m new cases of breast cancer worldwide pa[1] • 7.8m 5-year survivors[1]
Unmet medical need	• Earlier and more accurate screening and monitoring tests required for breast cancer • US$4.2b global diagnostics market[2]
Disruptive technology	• SubB2M is an engineered protein that specifically binds the pan-cancer biomarker Neu5Gc • Improved immunoassay for detection of Neu5Gc decorated CA15-3 • Increased sensitivity and specificity over existing assays
Intended use	• Aid in monitoring breast cancer treatment response and disease recurrence
Go to market approach	• LDT then IVD (510k process)

Key milestones



1. https://gco.iarc.fr/today/home; 2. https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market

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SubB2M/CA15-3 Breast Cancer test: Study BC04

Study objectives

- To evaluate the clinical performance of the SubB2M/CA15-3 test across all stages of breast cancer compared to healthy controls; and
- To compare the performance of the SubB2M/CA15-3 test to a leading approved CA15-3 test in the same samples in a clinical laboratory setting.

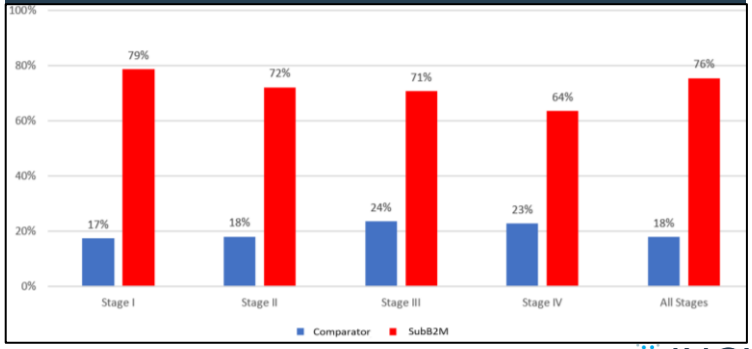
Study outcomes

- SubB2M/CA15-3 breast cancer test provides more accurate detection of breast cancer across all stages; and
- Significantly outperformed a leading approved CA15-3 test.

Table 1: SubB2M/CA15-3 and comparator 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%

Figure 1: Test Sensitivity by stage @95% Specificity



SubB2M/CA15-3 breast cancer test | data

Data from a 483-sample retrospective, case-control, **clinical validation study** demonstrated the SubB2M/CA15-3 breast cancer test significantly outperformed a leading approved CA15-3 test across all stages of breast cancer[1]

SubB2M/CA15-3 test provides more accurate detection of breast cancer across all cancer stages, demonstrating 81% sensitivity and 93% specificity, compared to a leading approved CA15-3 test[2]

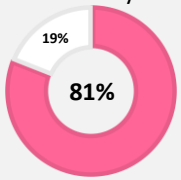
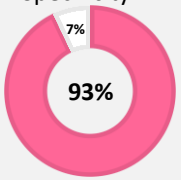
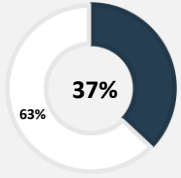
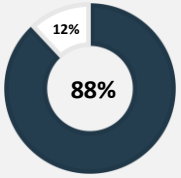
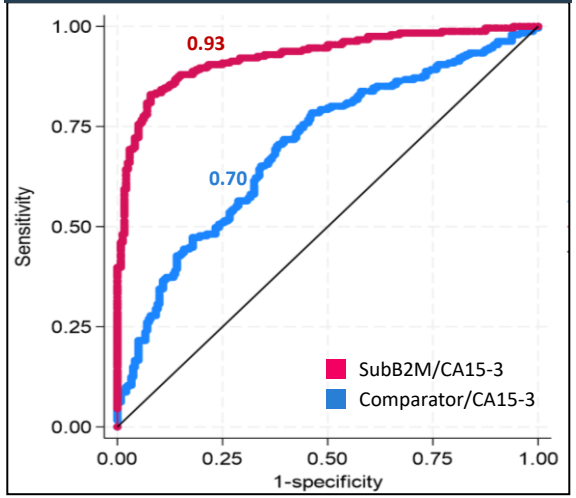
	Sensitivity:	Specificity:	
INOVIQ SubB2M/CA15-3			False positives: 7% False negatives: 19%
Comparator CA15-3			False positives: **12%** False negatives: **63%**

Figure: Receiver Operating Characteristic (ROC)[3] curves



NEXT: **Cross-sectional monitoring study** to evaluate performance of SubB2M-CA15-3 test to aid monitoring of treatment response and/or disease recurrence

1. Study performed by ResearchDx under Master Services Agreement (ASX: 5/4/22); 2. SubB2M Breast Cancer Test results (ASX: 27/6/23); 3. A Receiver Operating Characteristic (ROC) curve is method of estimating the performance of a test to classify samples as diseased or healthy. The area under the ROC curve (AUC) represents how well the test can correctly discriminate between case and control samples; the higher the AUC, the better the test.

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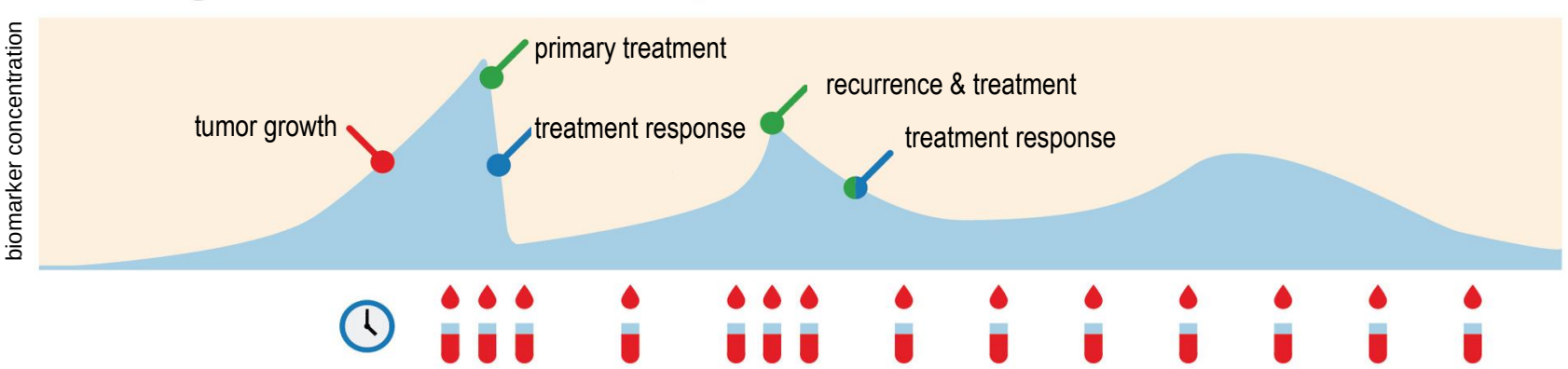
SubB2M/CA15-3 Breast Cancer test: Study BC-004

Next Steps

- Evaluate the performance of the SubB2M/CA15-3 test for monitoring treatment response and disease recurrence
- Does SubB2M/CA15-3 detect changes in tumor growth earlier than CA15-3 (and other biomarkers) and thus better inform clinical decision making
- Design: cross sectional cohort study



SubB2M/CA125 Ovarian Cancer Test | improved OC monitoring

Progressing towards clinical validation

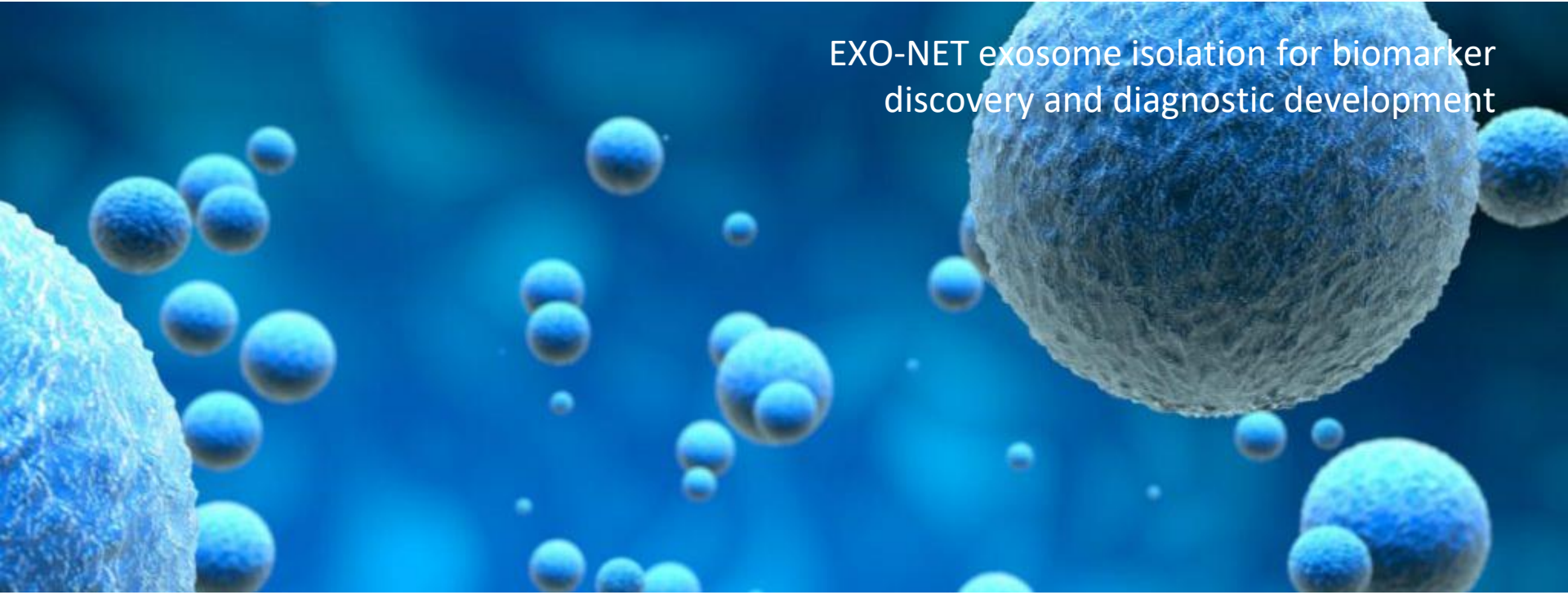
Ovarian cancer	• #8 cancer in women • 314k new cases of ovarian cancer worldwide pa[1] • 823k 5-year survivors[1]
Unmet medical need	• No approved test for early detection of OC in asymptomatic, average-risk women • US$1.8b global diagnostics market[2]
Disruptive technology	• SubB2M is an engineered protein that specifically binds the pan-cancer biomarker Neu5Gc • Based on existing immunoassays for CA125 • Increased sensitivity and specificity over existing assays
Intended use	• Aid in monitoring ovarian cancer treatment response and disease recurrence
Go-to-market strategy	• LDT then IVD (510k process)

Key milestones

Feasibility	Completed
Assay development	H1 FY24
Analytical validation	H1 FY24
Clinical validation	H1 FY24
Monitoring study	H2 FY24
LDT market ready	Jun 2024

1. Cancer Today (iarc.fr) ; 2. Ovarian Cancer Diagnostics Market Size Worth US$ 1.8 Bn by (globenewswire.com)

Pipeline products: EXO diagnostics



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Exosomes | Diagnostic and therapeutic potential

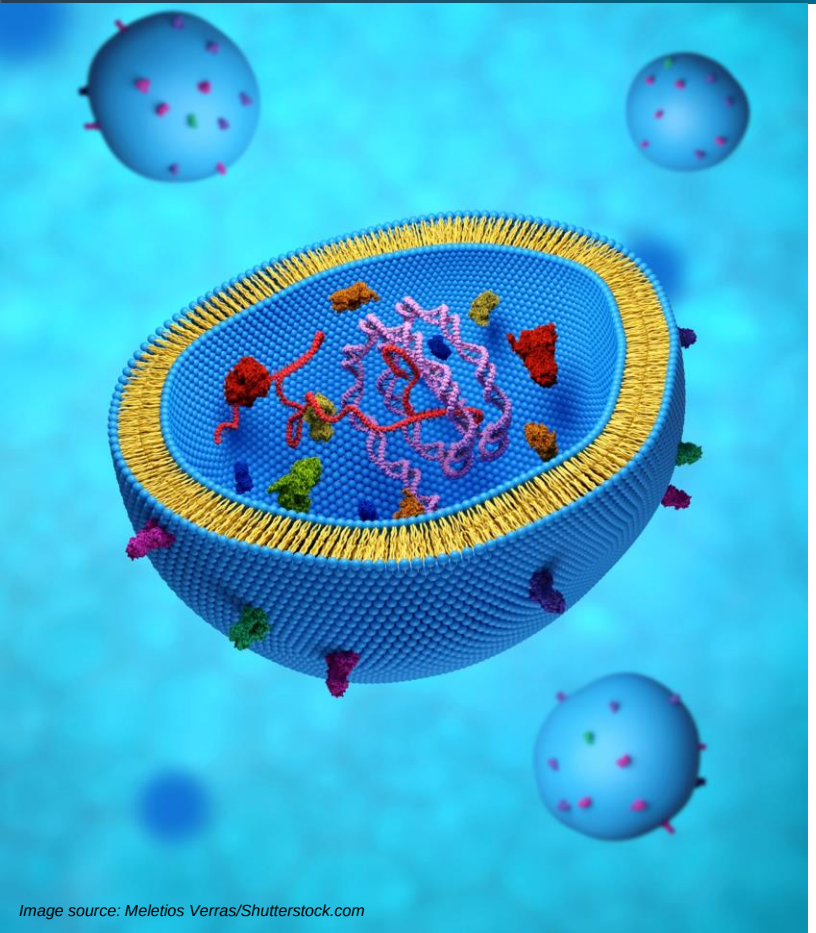

Image source: Meletios Verras/Shutterstock.com

- 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
- Exosomal **diagnostics and therapeutics** are being developed for oncology, neurology, cardiology, immunology, inflammatory diseases and other pathologies
- Commercial potential limited by lack of **fast, efficient and scalable exosome isolation** technologies

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EXO-NET® | Exosome isolation tools

- EXO-NET is an **immunoaffinity magnetic bead-based isolation system**
- **EXO-NET pan-exosome capture** is a *research use only* (RUO) tool for exosome isolation from plasma, serum, urine, saliva and cell-conditioned medium
- Meets unmet need for **fast, efficient and scalable** isolation of exosomes
- Suitable for exosome-based **biomarker discovery and diagnostic development** using manual and high-throughput (HT) solutions
- **HT EXO-NET** isolation system now available to enable processing of 96 samples per run within 40 minutes in a clinical laboratory[1]
- Expanding **EXO-NET pipeline** including TEXO-NET for tumour-derived EVs and NEURO-NET for brain-derived EVs
- Multiple **collaborations** validating EXO-NET utility in cancer, inflammatory, metabolic and neurodegenerative diseases[2]
- EXO-NET products **available for research-use or licensing** for commercial applications
- Joint marketing agreement with **Promega Corporation** to co-market INOVIQ's EXO-NET exosome capture technology and Promega Nucleic Acid Systems globally[3]

1. ASX: 28 July 2023; 2. ASX: 19 May 2023; 3. ASX: 6 July 2023

EXO-NET delivers fast, efficient and scalable exosome isolation

High Speed	Easy and convenient workflow with EV capture in 15-40 minutes via manual or automated processing
High Specificity	EV-surface antigen capture
High Purity	Reduced co-isolation of contaminants & high enrichment of EV RNA and protein markers
Reproducible	Demonstrated intra- and inter-assay reproducibility
Sample Versatility	Optimal solution for low-volume and rare samples (plasma, urine, saliva, cell conditioned medium)
Downstream Compatibility	Compatible for use with downstream applications (qPCR, Mass Spec, ELISA, FTIR, FACs)
Customisable	Ability to isolate specific EV subpopulations for use in target disease indications
Scalable	Suitable for high-throughput processing in routine pathology workflows

1. ASX: 15 May 2023 ; ASX: 28 July 2023

EXO-NET | Exosome services

CUSTOMISED EXO-NET TOOLS

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

EXOSOME ISOLATION

EV isolation using our EXO-NET powered, fully-automated, high-throughput platform[1]

BIOMARKER DISCOVERY

Biomarker discovery services to identify, evaluate and validate EV-based RNA and Protein biomarkers

DIAGNOSTICS DEVELOPMENT

EV-based clinical diagnostic, clinical trial assay and companion diagnostic development

1. ASX: 28 July 2023

EXO-Ovarian Cancer Test | World-first exosome-based screening test[1,2,3]

Moving towards clinical validation

Ovarian cancer	• #8 cancer in women • 314k new cases of ovarian cancer worldwide pa[4] • 823k 5-year survivors[4]
Unmet medical need	• No approved test for early detection of OC in asymptomatic, average-risk women • US$1.8b global diagnostics market[5]
Disruptive technology	• EXO-NET enables isolation of enriched exosomes for earlier and more accurate cancer detection • EXO-OC test in development as world-first EXO-NET enabled exosomal Multivariate Index Assay In Vitro Diagnostic
Intended use	• Screening of ovarian cancer in asymptomatic, high-risk women aged 50 years and over
Go-to-market strategy	• LDT then IVD (PMA process)

Key milestones

Feasibility	Completed
Assay development	Underway
Plasma-serum equivalence	Q1 FY24
Clinical validation study 5	TBD
LDT market ready	TBD

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)

EXO-Ovarian Cancer Test | data and plans

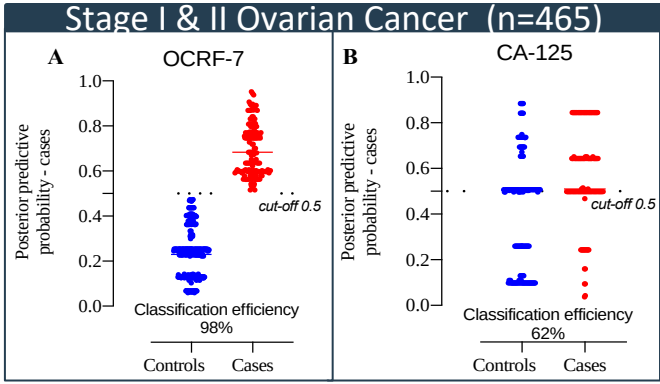
EXO-NET isolated EV ovarian cancer diagnostic

- **OC-ED003 Study:** retrospective case-control **Feasibility Study** in 97-plasma samples establishing EXO-NET superiority over SEC[1] for plasma EV biomarker discovery (miRNA and protein)
  - ✓ EXO-OC algorithm **correctly identified 91%** of samples[2]

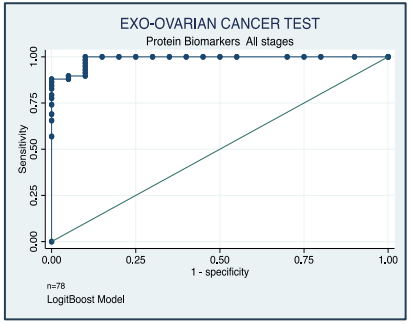
EXO-Ovarian Cancer Test

False positives: **5%**

False negatives: **10%**



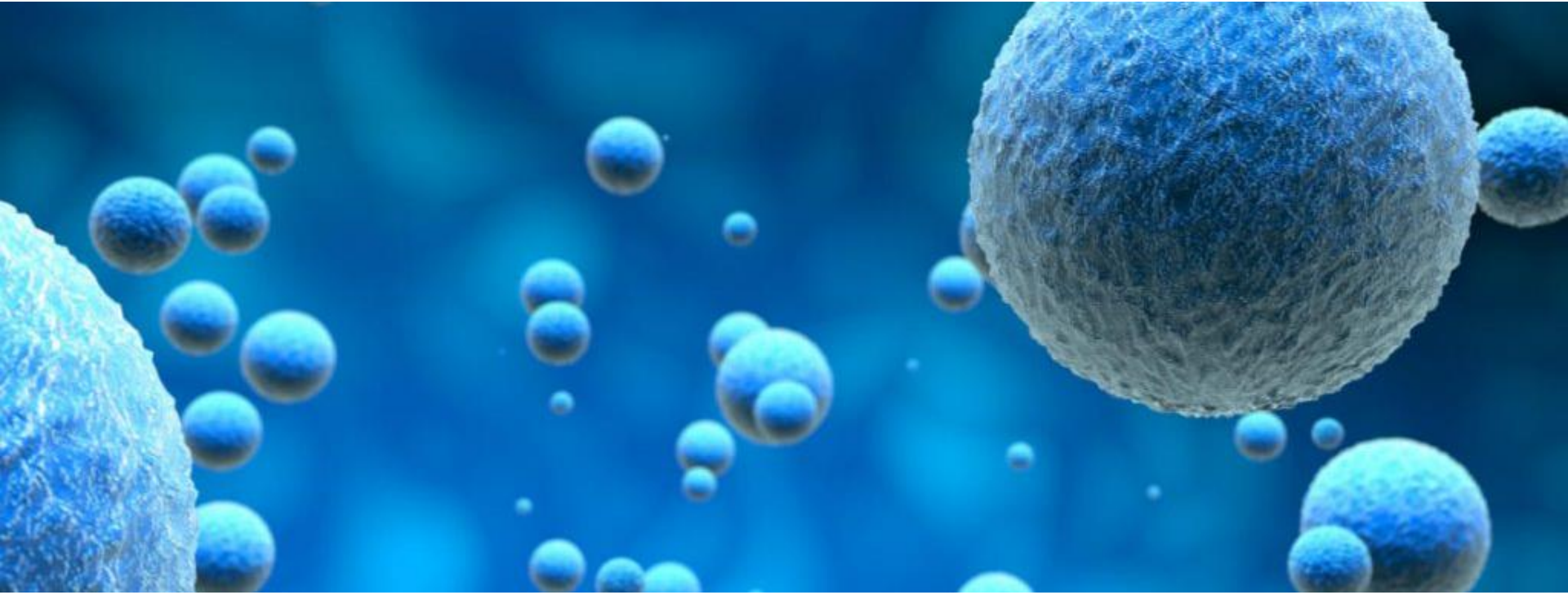
- **OC-ED004 Study:** Commenced 250-paired sample **equivalence study** to evaluate exosome-based biomarkers in plasma and serum from the same patients:
  - Equivalence will enable access to a readily available OC serum biobank under the MRFF grant for further EXO-OC development & validation



- **OC-ED005 Study:** Planned retrospective case-control **Clinical Validation** study to evaluate performance of EXO-OC Test to discriminate cancer across all OC cancer stages

1. SEC = Size Exclusion Chromatography; 2. Positive EXO-NET Results in OC-ED003 (ASX: 13/12/22)

Commercialisation and milestones



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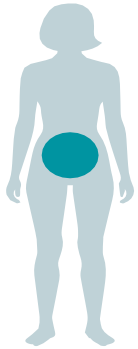
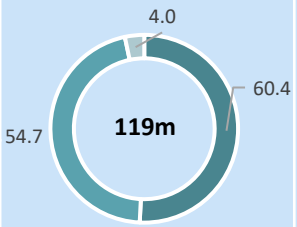
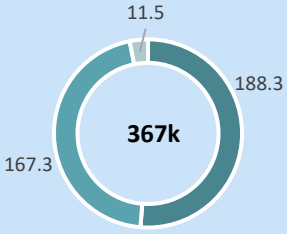
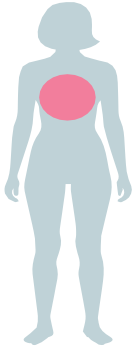
Market potential | Screening and monitoring tests



Ovarian cancer

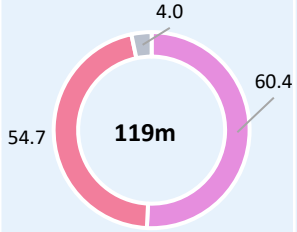
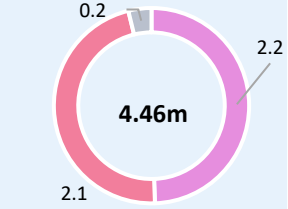
- EU5
- US
- AU

Statistics[1]	Eligible screening population[2]	Eligible monitoring population[3]	Global Market size[4,5]
Ovarian cancer incidence **52,638**	 (Millions of people)	 (Thousands of people)	(US$ billions)
Ovarian cancer prevalence **154,831**			



Breast cancer

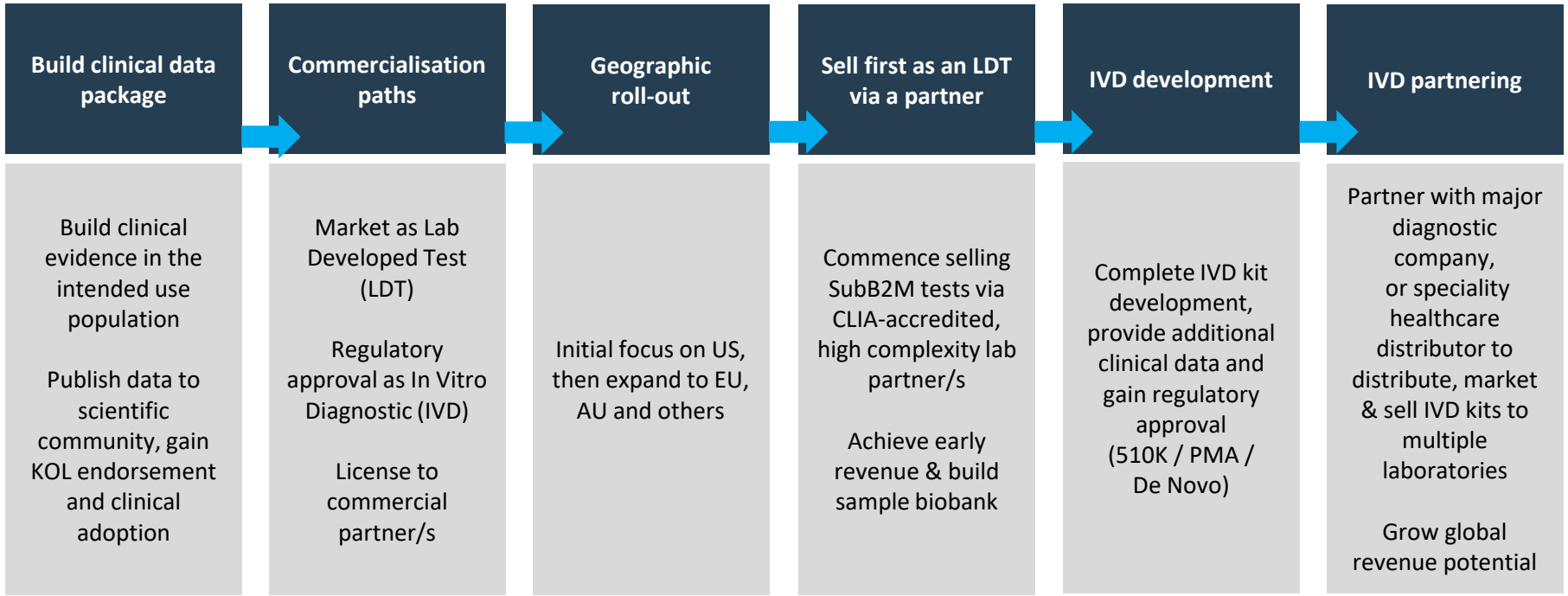
- EU5
- US
- AU

Breast cancer incidence **543,972**	 (Millions of people)	 (Millions of people)	(US$ billions)
Breast cancer prevalence **2,279,467**			

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

INOVIQ

SubB2M | Go-to-market strategy



510k = FDA clearance for Class II device; CLIA = Clinical Laboratory Improvement Amendments (high-complexity tests) ; CMS = Centers for Medicare and Medicaid Services; IVD = In Vitro Diagnostic; FDA = US Food & Drug Administration; LDT = Laboratory Developed Test; MDR = Medical Device Regulations; OC = Ovarian Cancer; PMA = FDA premarket approval for Class III device; KOL = Key Opinion Leader

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CY2023 milestones and catalysts

SubB2M/CA15-3 BC and EXO-NET OC programs moving towards key inflection points

H2 FY2023

- ✓ Results SubB2M/CA15-3 breast cancer study
- ✓ Results SubB2M/CA15-3 BC clinical validation study (n=483)
- ✓ EXO-NET data presented @ISEV2023 meeting

H1 FY2024

- ✓ EXO-NET co-marketing agreement with Promega
- ● Results of EXO-OC equivalence study in plasma and serum (n=250)
- ● Results SubB2M SPR feasibility study
- ● Results SubB2M/CA125 OC study
- ● TEXO-NET data @ ANZSEV23 meeting
- ● Results of SubB2M/CA15-3 BC monitoring study
- ● Progress SubB2M partnering
- ● Results of EXO-OC test study

Summary | Next generation diagnostic solutions advancing towards key milestones

1 Innovative Company

Focused on next-gen diagnostic and exosome solutions to improve health outcomes in cancer and other diseases

2 Patented Technology

Proprietary SubB2M & NETs technologies with multiple diagnostic and therapeutic applications

3 Strong Pipeline

Deep pipeline for detection of common and/or deadly cancers

4 Compelling Results

Data for SubB2M and exosome-based tests demonstrating earlier and more accurate detection for breast & ovarian cancers

5 Commercialized Products

Products in-market for exosome isolation and bladder cancer detection

6 Partnering for Growth

Commercialisation through partnering to deliver solutions to global markets

7 Experienced Leadership

Track record in healthcare leadership, exosome science, diagnostic development and commercialisation

8 Funding our Future

Cash of $7.8m as at 30 Jun 23 to fund operations and pipeline development

Contacts

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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.

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 ASX-listed 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
Chief Scientific Officer

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.

Strong IP portfolio covering technologies and applications

- Broad patent portfolio protecting IIQ's exosome platform, biomarker technologies and products
- IP owned or exclusively licensed
- 21 granted patents, 9 pending and 2 international (PCT) applications (at 24/3/23)
- Protection across key jurisdictions (including US, Europe, Asia & Australia)
- Registered trademarks for INOVIQ®, EXO-NET® & Acuris®

Patent Family	Title	Granted	Pending	Expiry
SubB2M				
PCT/AU2017/051230 (WO2018/085888)	Subtilase cytotoxin B subunit mutant	AU, JP, US	BR, CA, CN, EP, IN, KR, US (cont)	2037
PCT/AU2022/050470 (WO2022/236383)	Methods of analysing a sample			2042
Molecular NETs				
PCT/US2010/058086 (WO2011/066449)	Devices for detection of analytes	CN, US(cont1), US(cont2), US(cont3)	US(cont5)	2030
PCT/US2013/049779 (WO2014/011673)	Molecular Nets	EP		2033
PCT/AU2022/050428 (WO2022/232886)	Methods relating to tumour-derived extracellular vesicles			2042
BARD1				
PCT/FR01/02731 (WO/2002/018536)	Truncated BARD1 protein, and its diagnostic and therapeutic uses	US		2024
PCT/IB2011/054194 (WO/2012/038932)	Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof	EP, US, US (cont)		2031
EP14002398.7	Non-coding RNA as diagnostic marker and treatment target	US		2035
hTERT				
PCT/AU2015/050060 (WO2015/120523)	Method of resolving inconclusive cytology to detect cancer	AU, CN, EP, IL, JP, US, US(cont)		2035
PCT/AU2016/050764 (WO2017/027928)	Method of detecting cancer in morphologically normal cells	JP	US	2036

cont = continuation; div = divisional