



SubB2M/CA15-3 clinical validation data

Webinar presentation



ASX: IIQ | 29 June 2023



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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 across multiple applications



Deep pipeline

Diverse, multi-stage, exosome research and diagnostic pipeline



Compelling data

For exosome isolation tools, and diagnostics for breast and ovarian cancers



Commercial products

In-market products for exosome isolation and bladder cancer detection



Partnering for growth

Partnering with KOLs and Industry to deliver clinical and commercial outcomes



INOVIQ snapshot

- **Founded in 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 Minnesota, US
- **18 employees** including 9 R&D staff with 7 PhDs
- **Expertise** in research, development, clinical testing and commercialisation
- **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

12-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\$0.880-0.385
Share price ²	A\$0.710
Market capitalisation ²	A\$65.3m
Cash at bank ¹	A\$8.8m
Ave monthly cash burn ³	A\$619k

Major shareholders (as at 27 June 2023)

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

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

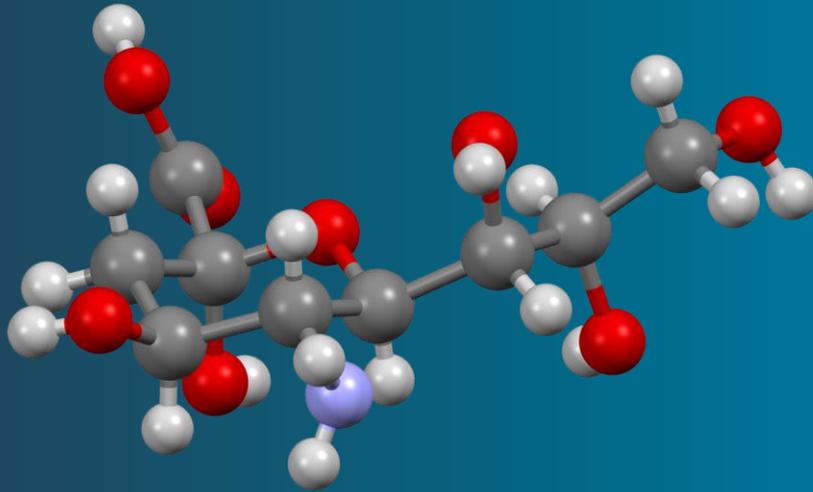


EXO tools/Dx SubB2M Dx

PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL DEVELOPMENT	MARKET
hTERT ¹	Bladder Cancer	ICC	Adjunct to cytology				USA
SubB2M-BC	Breast Cancer	Immunoassay	Monitoring	LDT			Dec-23
SubB2M-OC	Ovarian Cancer	Immunoassay	Monitoring	LDT			2H FY24
SubB2M-SPR	Multi-cancer	SPR	Pre-screening				
EXO-OC ²	Ovarian Cancer	Multiomic	Screening				
EXO-NET RUO	pan-EV capture	Immunocapture	Research tool				AU/USA
TEXO-NET RUO	td-EV capture	Immunocapture	Research tool				
NEURO-NET RUO	bd-EV capture	Immunocapture	Research tool				

SubB2M diagnostics

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



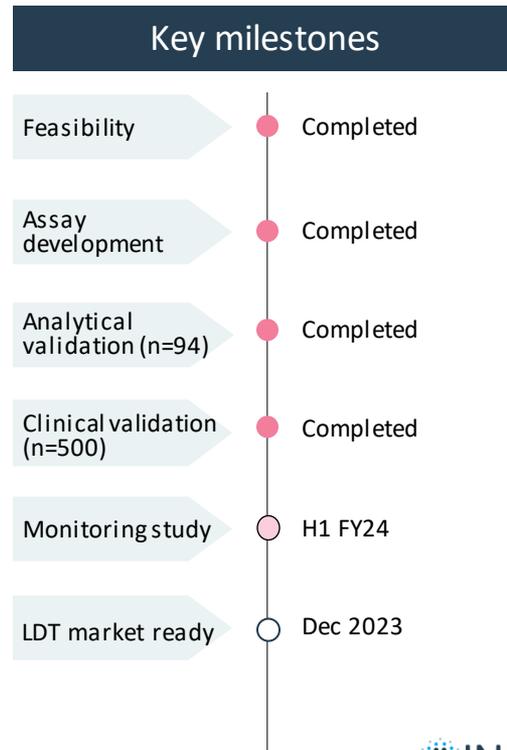
neuraminic acid





Clinical-stage and progressing towards market-ready by end 2023

Breast cancer	<ul style="list-style-type: none">• #1 cancer in women• 2.3m new cases of breast cancer worldwide pa¹• 7.8m 5-year survivors¹
Unmet medical need	<ul style="list-style-type: none">• Earlier and more accurate screening and monitoring tests required for breast cancer• US\$4.2b global diagnostics market²
Disruptive technology	<ul style="list-style-type: none">• SubB2M is an engineered lectin 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	<ul style="list-style-type: none">• Aid in monitoring breast cancer treatment response and disease recurrence
Go to market approach	<ul style="list-style-type: none">• LDT then IVD (510k process)





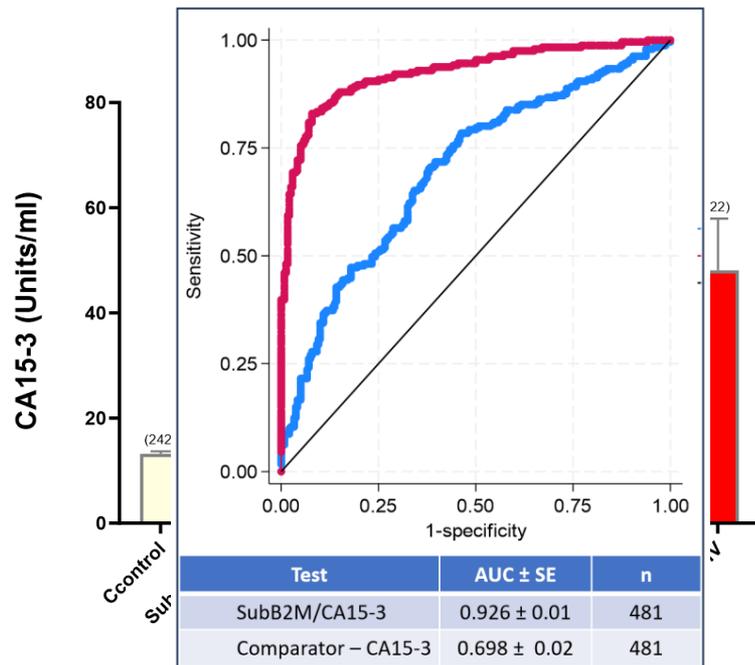
Study objectives

- 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.

Receiver Operating Characteristic Curve

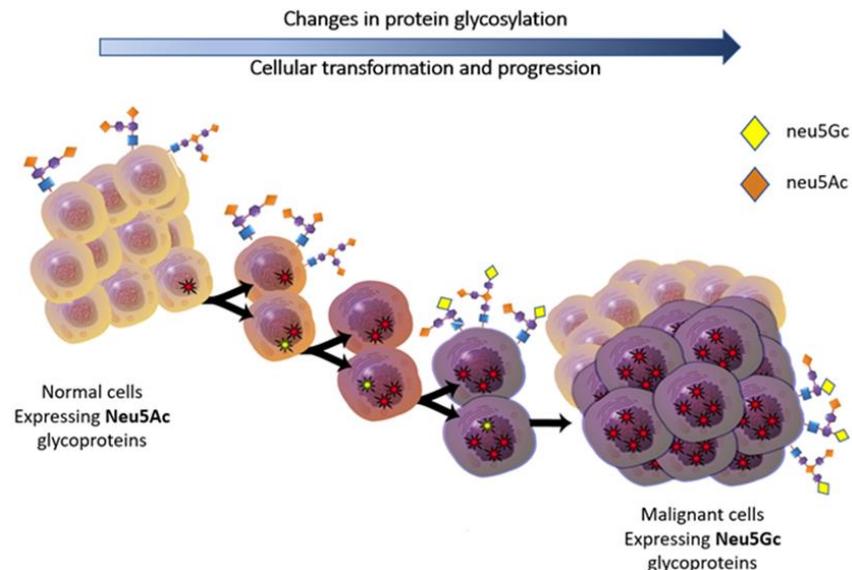


Data represent mean and standard error of the mean (n)



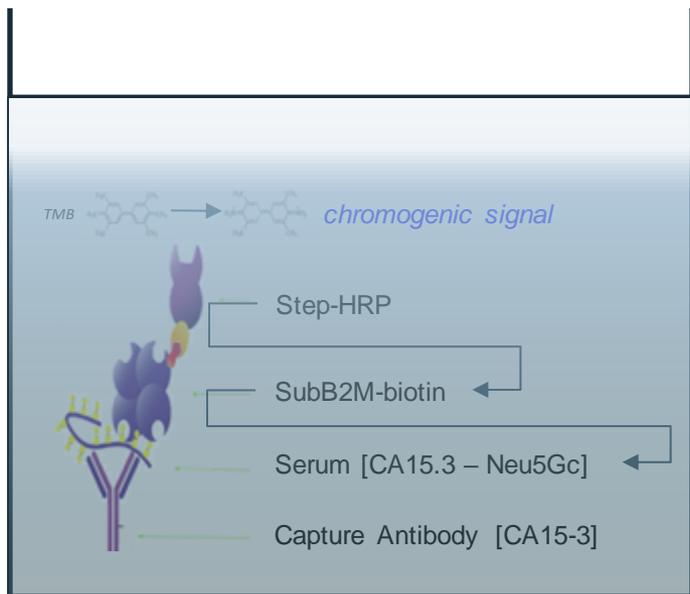
Study rationale

- 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





SubB2M ELISA Format

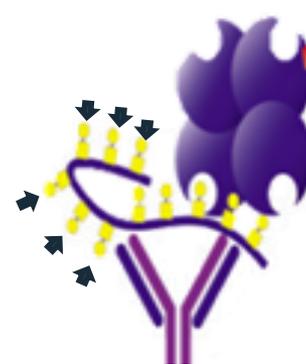


TMB - 3,3',5,5'-Tetramethylbenzidine

Why should SubB2M improve assay performance?

Multiple Neu5Gc binding sites on target [CA15.3], therefore, more signal generated which increases the sensitivity of the test.

Cancer cells preferentially use Neu5Gc to decorate the proteins they make (including CA15-3 and CA125), therefore, using SubB2M (that binds to Neu5Gc) makes the test more specific.

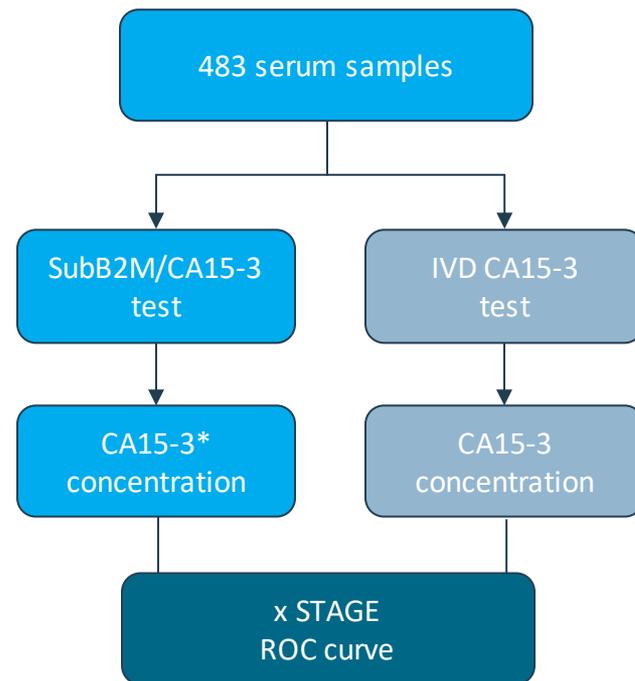


SubB2M multiple binding sites increases sensitivity



Study design

- Retrospective case : control design (1:1, bio-banked samples)
- Serum sample healthy controls (242) and all stages of breast cancer (I=75, II=72, 3=72, III=72, IV = 22)
- Using SubB2M, we developed a CA15-3 ELISA that only detects CA15-3 produced by cancer cells
- The concentration of CA15-3 was measured using the SubB2M/CA15-3 test and by IVD approved CA15-3 test run in clinical pathology laboratory
- The results from the two tests were then compared:
 - By disease stage
 - ROC curve analysis





Results

- INOVIQ's SubB2M/CA15-3 test demonstrated superior diagnostic accuracy compared to a leading CA15-3 IVD in a 483-sample case-control study

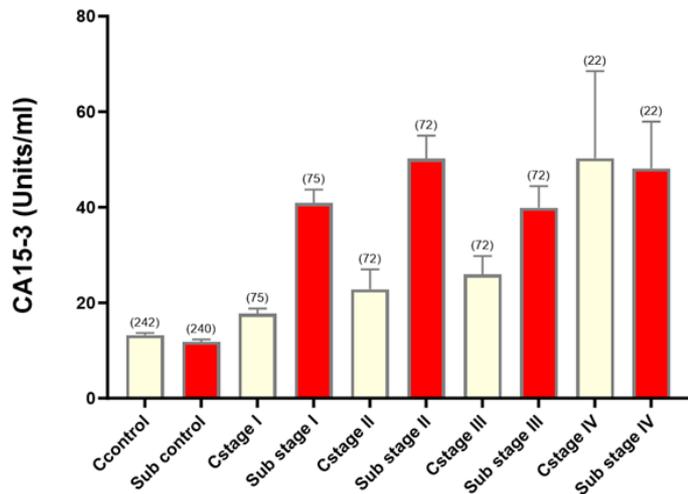
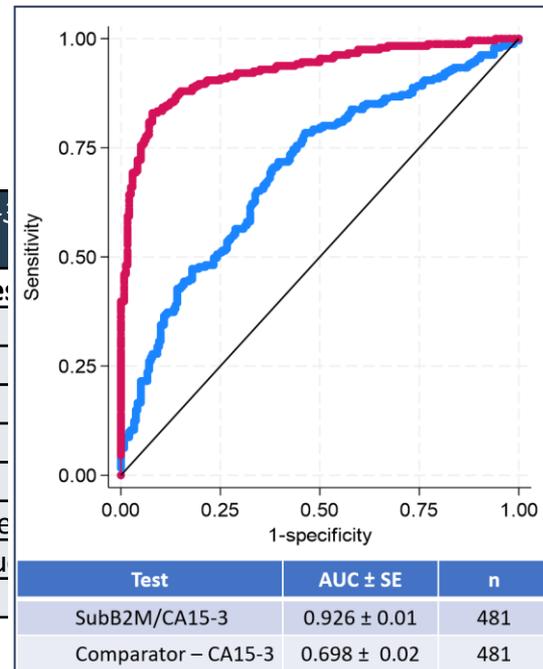


Table 1: SubB2M/CA15-3 performance summary	
Breast Cancer All Stage:	
AUC	0.926 ± 0.01
sensitivity	0.926 ± 0.01
specificity	0.698 ± 0.02
false negative rate	0.074 ± 0.01
false positive rate	0.302 ± 0.02
positive predictive value	0.926 ± 0.01
negative predictive value	0.698 ± 0.02
overall accuracy	0.812 ± 0.01

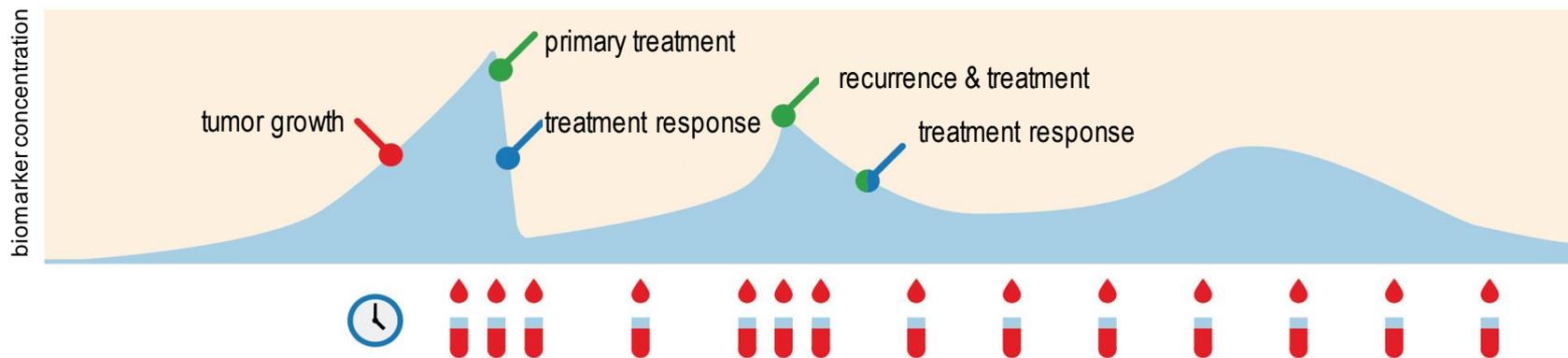
Receiver Operating Characteristic Curve





Next Steps

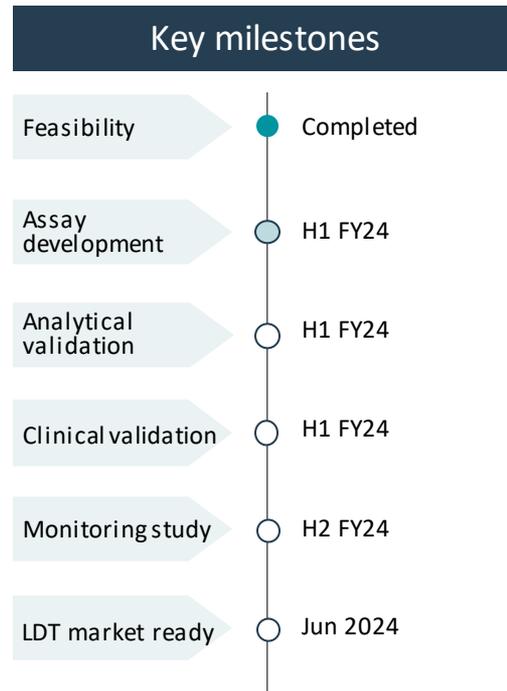
- Evaluate the performance of the SubB2M/CA15-3 test for monitoring treatment response and disease recurrence.
- Does SubB2M/CA15-3 detect changes in tumor growth earlier than CA15-3 (and other biomarkers) and thus better inform clinical decision making
- Design: cross sectional cohort study



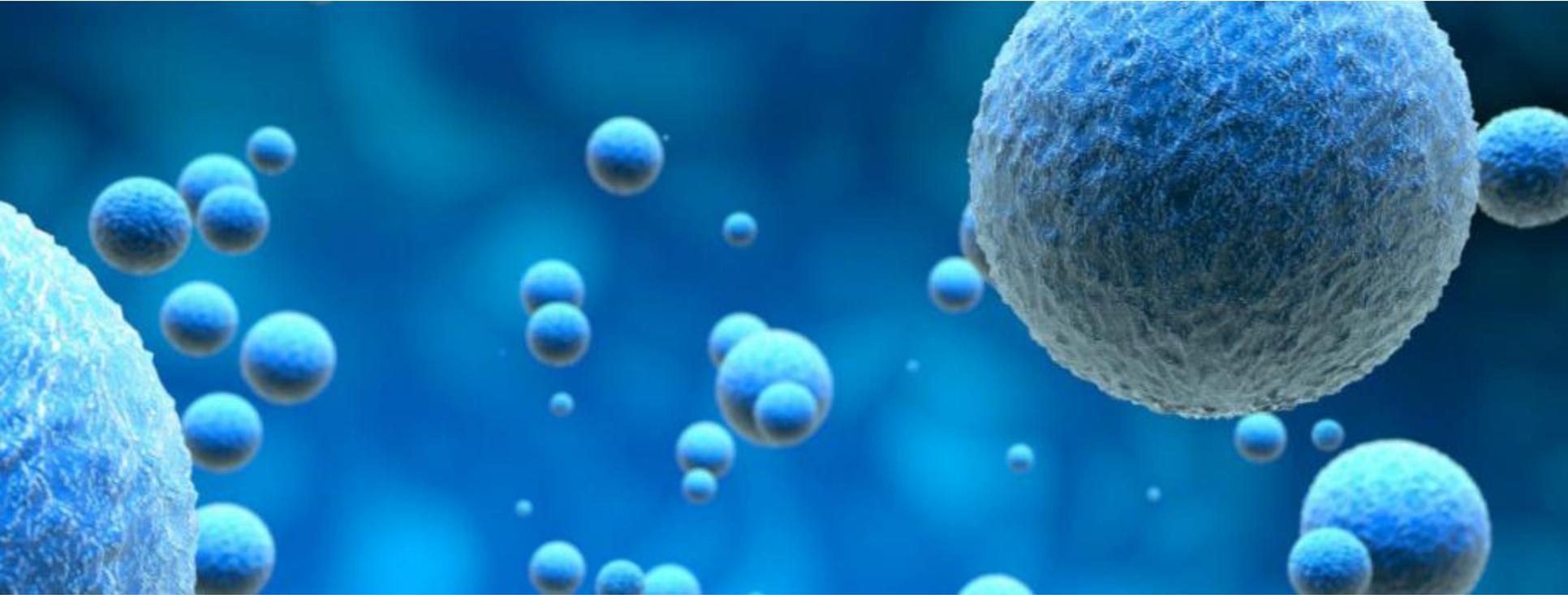


Progressing towards clinical validation

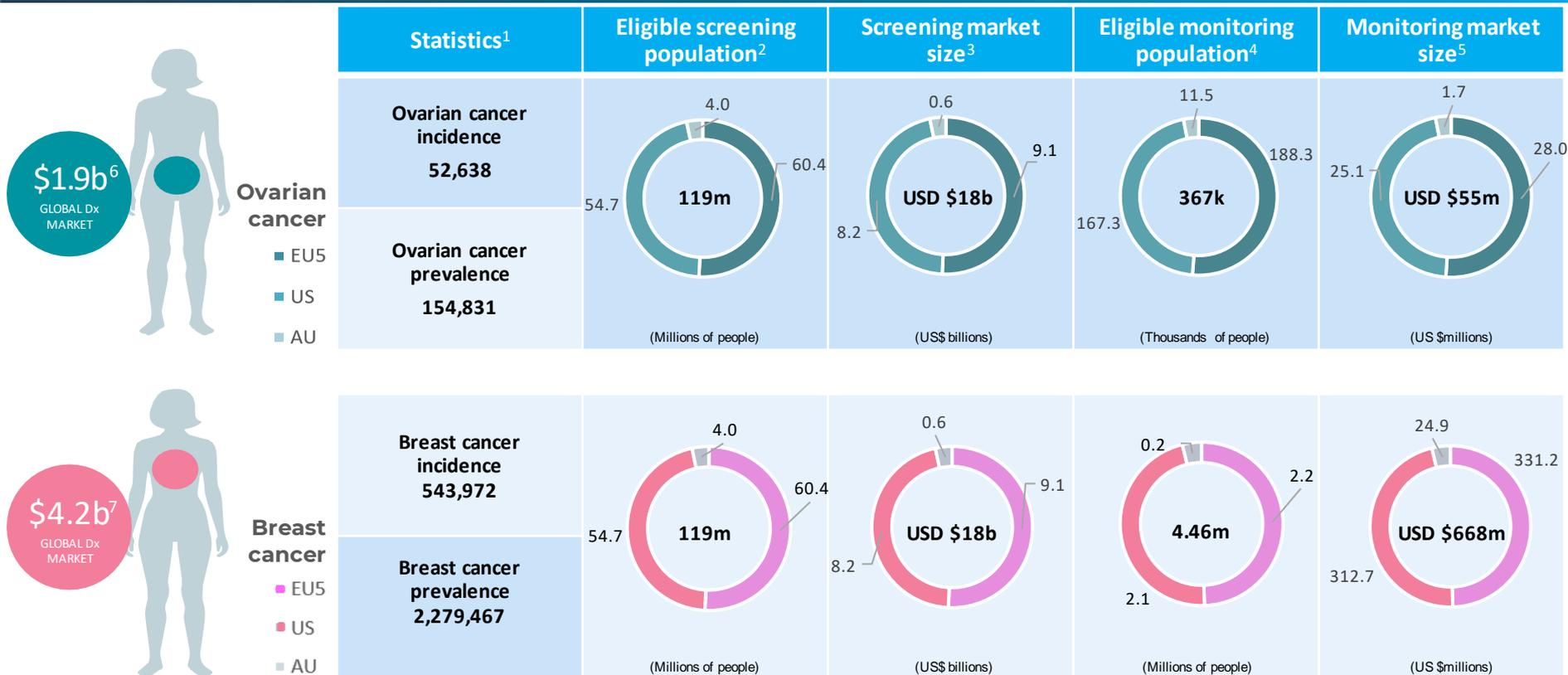
Ovarian cancer	<ul style="list-style-type: none">• #8 cancer in women• 314k new cases of ovarian cancer worldwide pa¹• 823k 5-year survivors¹
Unmet medical need	<ul style="list-style-type: none">• No approved test for early detection of OC in asymptomatic, average-risk women• US\$1.8b global diagnostics market²
Disruptive technology	<ul style="list-style-type: none">• SubB2M is an engineered lectin that specifically binds the pan-cancer biomarker Neu5Gc• Based on existing immunoassays for CA125• Increased sensitivity and specificity over existing assays
Intended use	<ul style="list-style-type: none">• Aid in monitoring ovarian cancer treatment response and disease recurrence
Go-to-market strategy	<ul style="list-style-type: none">• LDT then IVD (510k process)

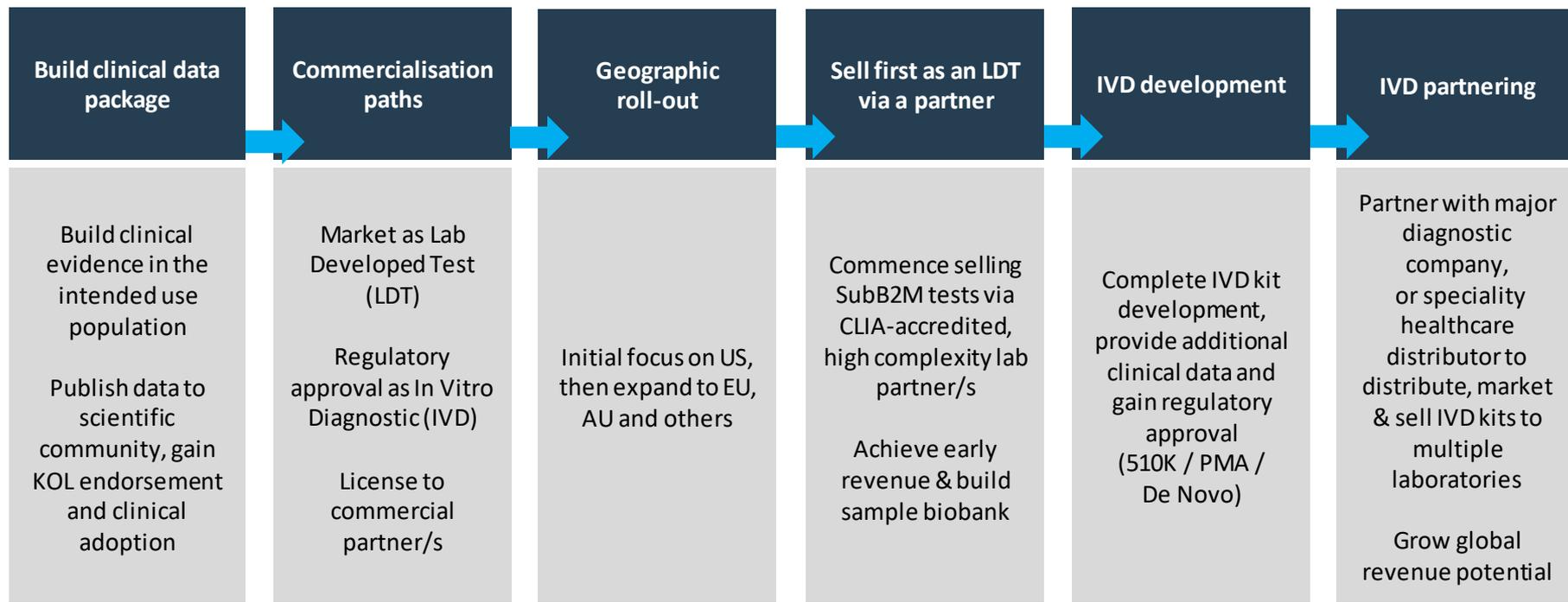


SubB2M commercialisation



Market potential | Screening and monitoring tests







2H FY2023

- ✓ Results SubB2M/CA15-3 breast cancer study 1
- ✓ Results SubB2M/CA15-3 BC clinical validation study 2 (n=483)
- ✓ EXO-NET data presented @ISEV2023 meeting
- Results of EXO-Ovarian Cancer test study 4 (n=250)

1H FY2024

- Results SubB2M SPR feasibility study 1
- Results SubB2M/CA125 OC study 1
- Progress EXO-NET collaborations/partnering
- TEXO-NET data @ ANZSEV23 meeting
- Results of SubB2M/CA15-3 BC monitoring study 3
- Progress SubB2M partnering
- Results of EXO-OC screening test study 5



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 \$8.8m as at 31 Mar 23 to fund operations and pipeline development



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