

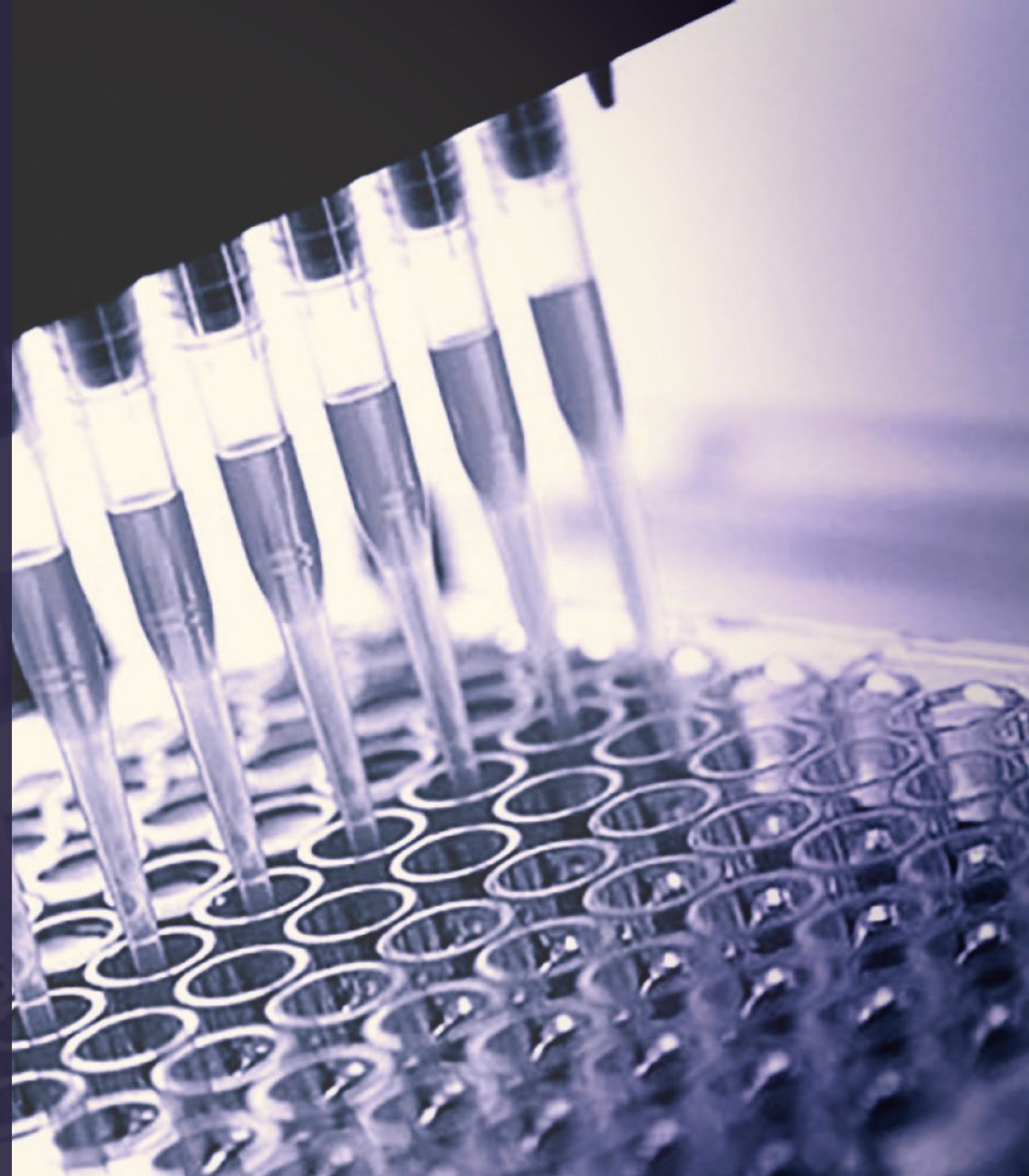
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Detecting cancer earlier to save lives

Annual General Meeting
29 November 2021

CEO Presentation



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Company overview

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BARD1 Life Sciences (ASX: BD1)

- Lifesciences company initially focused on earlier cancer detection
- Innovative technologies with strong IP protecting methods & use
- Multi-product pipeline for breast, ovarian & other cancers targeting US\$11b global markets
- Compelling POC results for lead SubB2M tests for breast & ovarian cancers¹
- Strong cash position to commercialise lead products as LDTs
- Products in-market for bladder cancer² & exosome research

Board and management

	Dr Geoff Cumming Chairman		Dr Greg Rice Chief Scientific Officer
	Max Johnston Non-Exec Director		Tony Di Pietro CFO / Company Sec
	Phillip Powell Non-Exec Director		Susan Belzer Development Director
	Prof Allan Cripps Non-Exec Director		Dr Wayne Jensen R&D Director
	Dr Leearne Hinch Chief Executive Officer		Dr Emily Stein Technology Director (NETs)

Financial information (ASX:BD1)

Ordinary shares	91,994,920
Share price (26/11/21)	A\$1.040
Market capitalisation	A\$95.6m
Cash position (30/9/21)	A\$20.4m
Ave monthly cash burn (Q1 FY22)	A\$593k
Top 20 Shareholders (26/11/21)	36.4%

Share price performance (Past 12 months)



Dx = Diagnostics; POC = Proof of Concept;; LDT = Laboratory Developed Test;

¹ SubB2M proof-of-concept data using SPR; ² Adjunct to urine cytology to assist the detection of bladder cancer

Key achievements

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Commercial

- **hTERT** revenues steady at \$550k pa, new lab users gained in US, and Sth Korean registration achieved
- **EXO-NET RUO** product launched and multiple evaluations progressed for exosome research applications (incl. Minomic, UQ)
- Multiple **collaboration & partnering** discussions underway with academia & industry
- **Strengthened IP** portfolio with multiple patents granted, new patent applications filed & new trade marks registered and filed
- **ISO 13485** re-certification

Research & Development

- Progressed **SubB2M immunoassay** program with initial feasibility achieved for SubB2M-CA125 test for ovarian cancer
- Preliminary feasibility results for **SubB2M IHC** for diagnosis of breast cancer in tissue biopsies
- Multiple **EXO-NET** evaluations by independent research groups and internal data generated for competitor comparison paper
- Completed evaluations of **BARD1 AAb test** in ovarian cancer samples on Luminex platform at UNIGE & Griffith Uni showing reproducibility of data
- Multiple **publications and presentations** for SubB2M SPR assay, BARD1 AAb test, and EXO-NET

Corporate

- **Acquisition & integration of Sienna** with focus on realising synergies, prioritising R&D pipeline & growing revenue
- **1:30 share consolidation** to improve register management
- **Capital raising of \$18.4m** to fund development & commercialisation of lead programs
- **Strengthened R&D leadership** with appointment of Dr Greg Rice PhD as CSO

Financial

- **Cash balance of \$20.4m** at 30 September 2021
- **Cost-savings** of over \$1.1m realised from operational synergies & restructuring post-merger

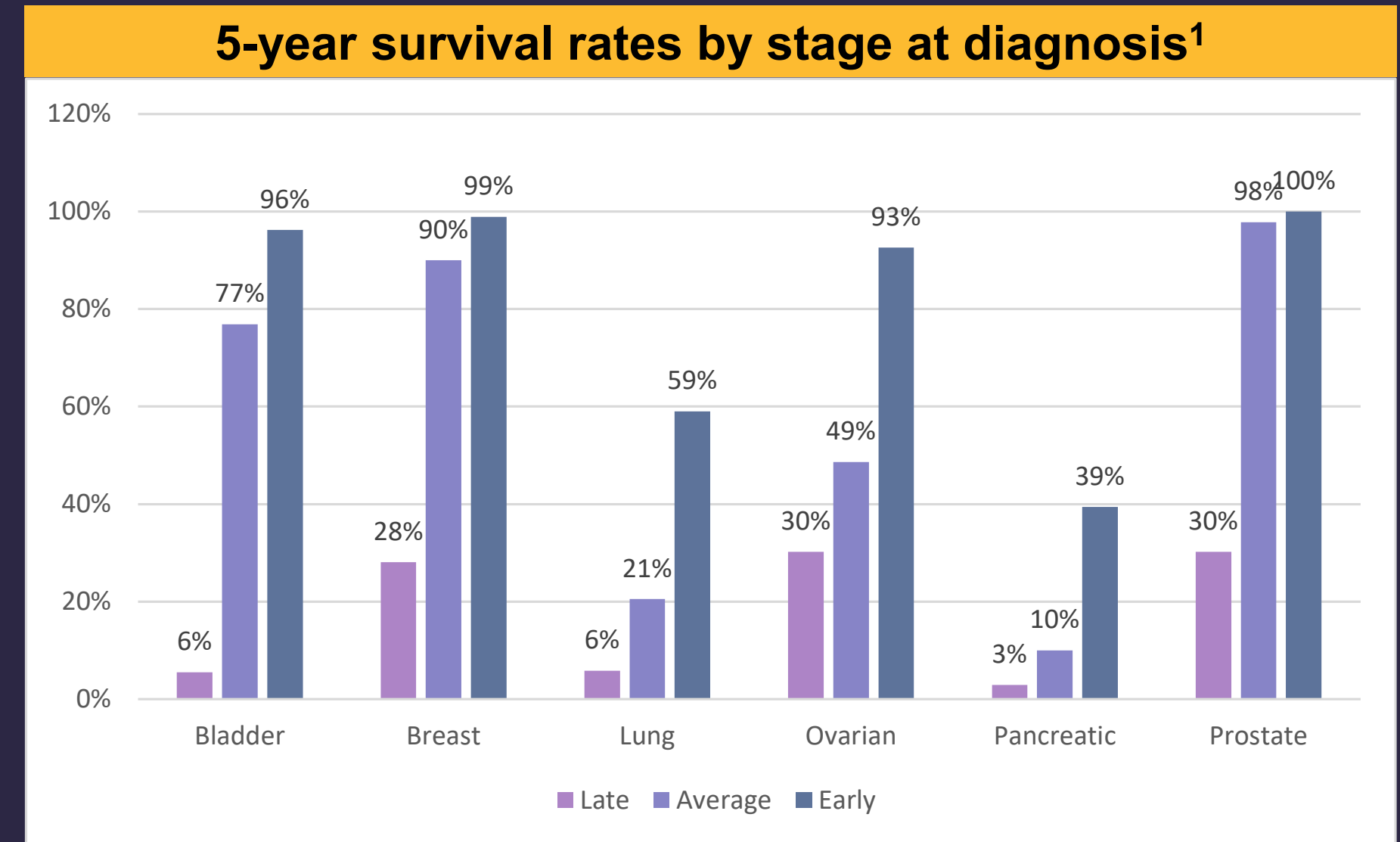
Unmet need for earlier cancer detection

Problem

- Detection of early-stage cancers is often associated with high false-positives &/or lack of sensitivity
- Cancers often detected at late-stage after symptoms have appeared resulting in poor prognosis
- Current tests can have safety, cost and convenience issues reducing test participation rates

Unmet need

- Unmet need for non-invasive, accurate and reliable diagnostic tests for earlier detection of cancer
- Earlier detection improves treatment options, patient outcomes & survival¹



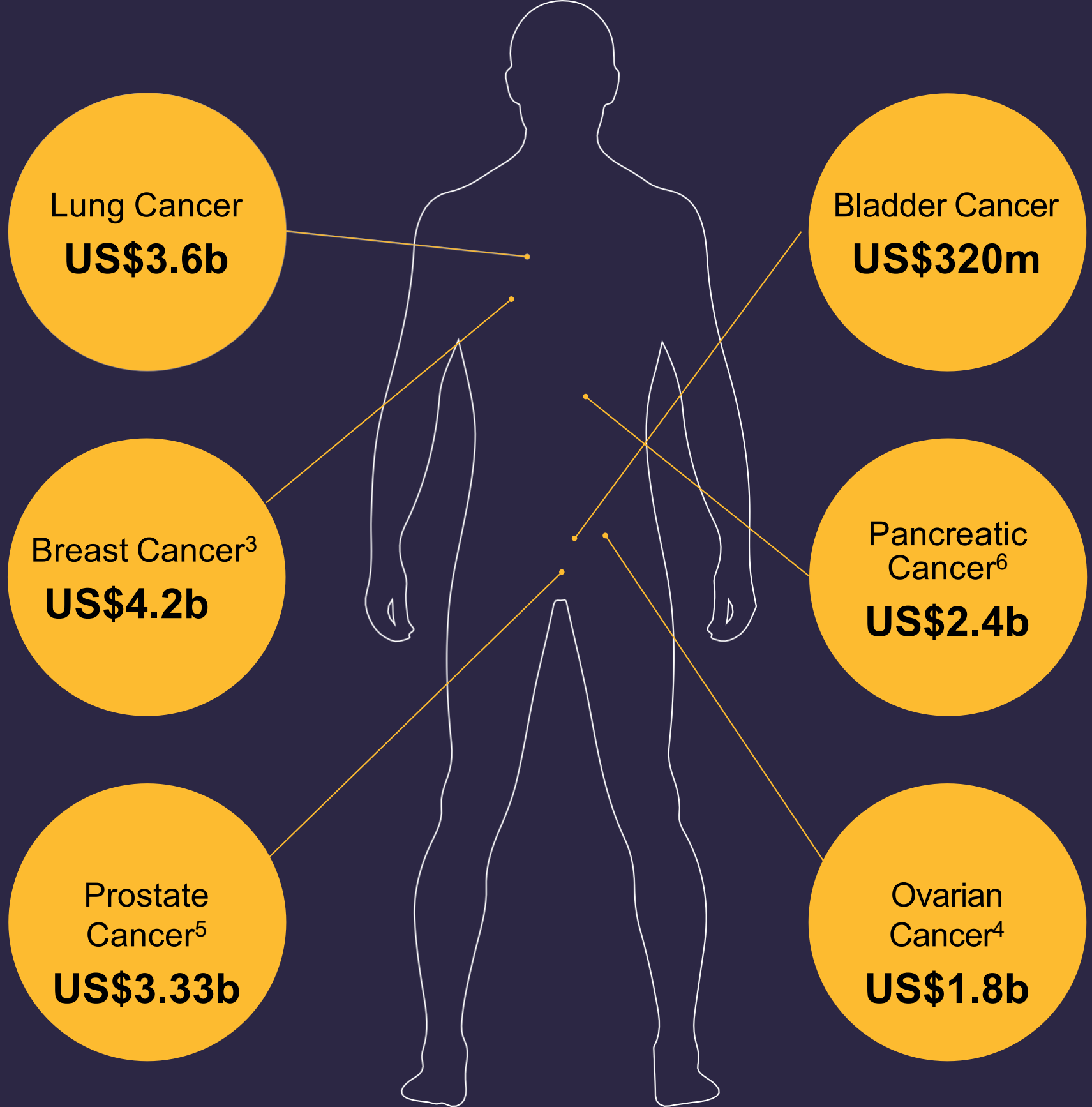
¹ SEER 18 2010-2016

Global cancer diagnostics market

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- Global cancer burden: 50.6m survivors, 19.3m new cases and 10.0m deaths p.a.¹
- Global cancer diagnostics market valued at US\$250b²
- BARD1 is targeting markets worth over US\$11b for some of the world's most common and deadliest cancers

#	Cancer	Prevalence	Incidence	Deaths
1	Breast	7,790,717	2,261,419	684,996
3	Prostate	4,956,901	1,414,259	375,304
17	Ovarian	823,315	313,959	207,252
22	Pancreatic	379,958	495,773	466,003



Breast cancer | US screening market potential

- World's most common cancer: 2.3m new cases & 685k deaths pa¹
- US: 3.7m survivors, 234k new cases & 43k deaths pa^{1,2}
- Life-time risk of 12.9% , increases to 55-70% with *BRCA1* & 45-69% with *BRCA2* mutations²
- Screening using mammography recommended for average-risk women and those with a family history or genetic mutations³
- Issues with high false positives, safety and self-exclusion due to discomfort, inconvenience and cost
- CA15.3 test approved for monitoring BC: sensitivity <50-75% and specificity 85%
- Unmet need for an accurate & reliable blood test for earlier detection of BC
- Early detection can improve QOL, treatment options & survival (from 29% at late-stage to 99%)²

		US Breast Cancer Market pa (USD)		
		10%	20%	30%
Indicative Price	Market Penetration			
	\$125	\$0.4 bn	\$0.8 bn	\$1.1 bn
	\$250	\$0.8 bn	\$1.5 bn	\$2.3 bn
	\$500	\$1.5 bn	\$3.0 bn	\$4.5 bn

Key Assumptions (US market):

- Target population: 60.5m women aged 45 - 74 years^{3,4}
- Screening frequency: biennial⁴
- Price: indicative pricing only⁵

Ovarian cancer | US screening market potential

- World's deadliest gynaecological cancer: 314k new cases & 207k deaths pa¹
- US: 235k survivors, 24k new cases & 14k deaths pa^{1,2}
- Life-time risk of 1.2%, increases to 35-70% with *BRCA1* mutation^{2,4}
- Average 5-year survival 49% due to late-stage detection after symptoms have appeared (57%)²
- Screening not recommended in ave-risk women, whereas CA125 test + TVUS may be offered to high-risk women⁴
- CA125 test approved for monitoring OC: sensitivity 50-75% and specificity 80%
- Unmet need for an accurate & reliable blood test for earlier detection of OC
- Early detection can improve QOL, treatment options & survival (from 30% at late-stage to 93%)²

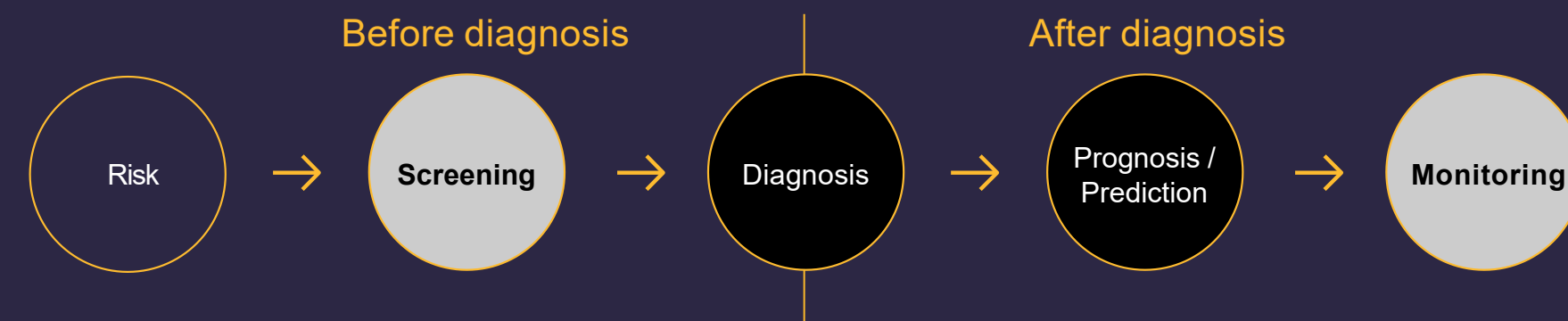
		US Ovarian Cancer Market pa (USD)		
		10%	20%	30%
Indicative Price	Market Penetration			
	\$125	\$0.6 bn	\$1.3 bn	\$1.9 bn
	\$250	\$1.3 bn	\$2.5 bn	\$3.8 bn
	\$500	\$2.5 bn	\$5.1 bn	\$7.6 bn

Key Assumptions (US market):

- Target population: 50.5m women aged 50 - 74 years³
- Screening frequency: annual
- Price: indicative pricing only⁵

Product and pipeline portfolio

- Commercial products for bladder cancer¹ & exosome research
- Multi-product pipeline focused on detection & monitoring of cancer
- Lead pipeline products for monitoring breast & ovarian cancer



PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	PRECLINICAL DEVELOPMENT	CLINICAL DEVELOPMENT	MARKETING AUTHORISATION
hTERT	Bladder Cancer	ICC	Adjunct to cytology	→			In-market
EXO-NET-RUO	Exosome Capture		Research tool	→			In-market
SubB2M-BCM	Breast Cancer	Immunoassay	Monitoring	→	LEAD PIPELINE PRODUCTS		2023
SubB2M-OCM	Ovarian Cancer	Immunoassay	Monitoring	→			2023
SubB2M-PCS	Prostate Cancer	Immunoassay	Detection	→			**
SubB2M-PaCS	Pancreatic Cancer	Immunoassay	Detection	→			**
BARD1-Ovarian	Ovarian Cancer	Immunoassay	Detection	→			**
BARD1-Breast ²	Breast Cancer	Immunoassay	Detection	→			
BARD1-Lung ²	Lung Cancer	Immunoassay	Detection	→			

RUO = Research Use Only; **Dates will be released when projects are further advanced; ICC = Immunocytochemistry;

¹ Adjunct to urine cytology to assist the detection of bladder cancer; ² Progression subject to further assay design, development & validation

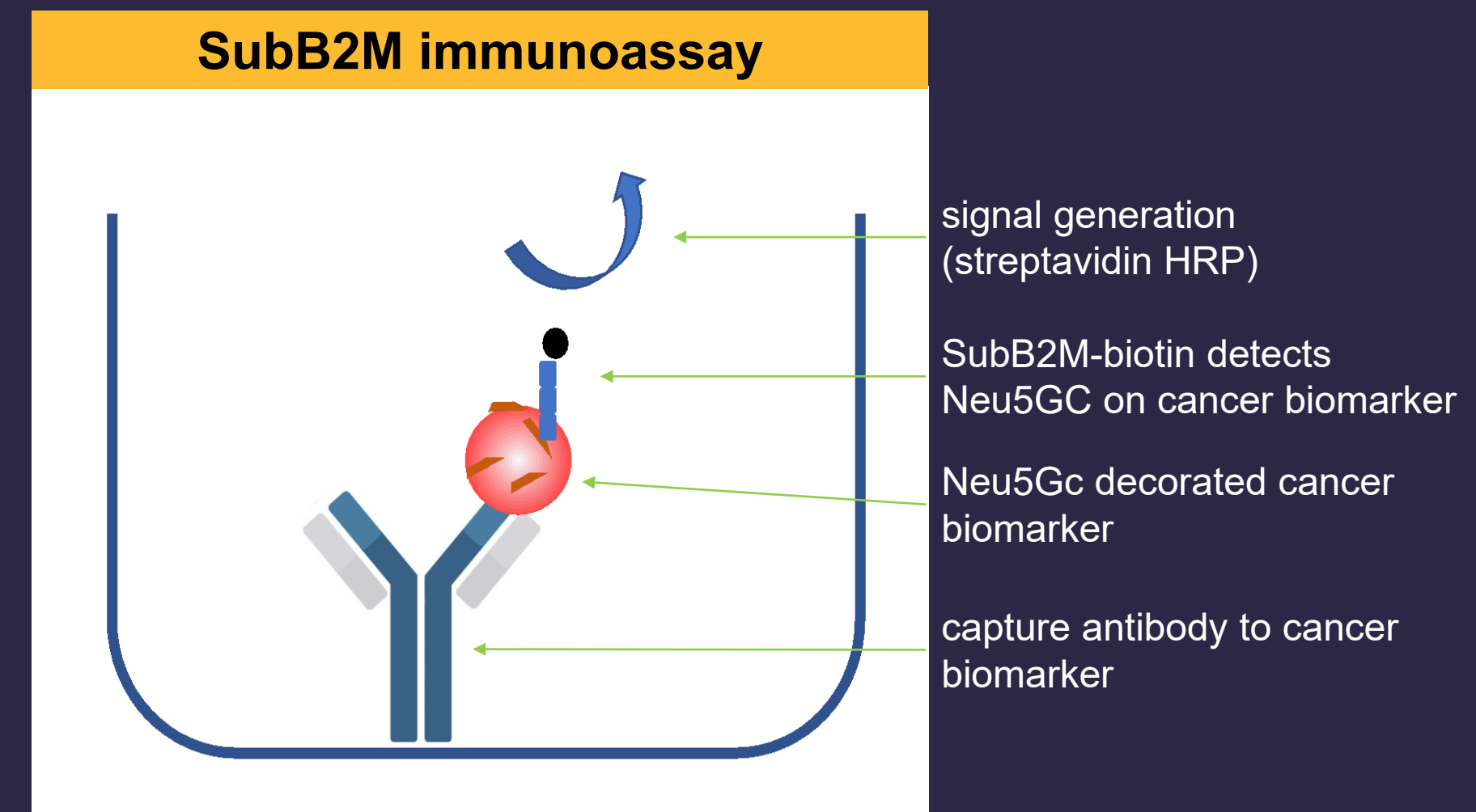
SubB2M™ | technology and test method

Game-changing technology for monitoring and detection of cancer



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- SubB2M protein detects a unique cancer marker **Neu5Gc** found in human cancer tissues, cells & biofluids¹
- **Exclusive worldwide licence** to SubB2M technology for diagnostic applications²
- **Multiple applications** for diagnosis of various cancers (breast, ovarian, prostate, pancreatic, others)
- Potential to **improve the specificity of existing cancer biomarker tests** with next generation SubB2M tests for monitoring and/or detection of ovarian (CA125), breast (CA15.3), prostate (PSA) and other cancers
- Focused on developing SubB2M tests for monitoring of **breast and ovarian cancers**³
- Currently optimising assay for **transfer to CRO for commercial development** on immunoassay platform



Commercialisation | goals and strategy

GOAL is to develop and commercialise accurate and reliable blood tests for earlier detection and monitoring

Develop SubB2M-based immunoassay	<ul style="list-style-type: none">• Prioritise development of SubB2M immunoassay for monitoring breast and ovarian cancers on platform compatible with high-throughput laboratory workflow (ELISA / bead-based assays)• Evaluate development SubB2M test on small foot print SPR instrumentation• Development of SubB2M IHC for diagnosis of breast, melanoma and/or other tissue biopsies
Advance lead Dx pipeline	<ul style="list-style-type: none">• Transfer development from academic to CRO partner• Assay development of SubB2M assay and platform• Analytical validation of test/s to ensure robust, reproducible and reliable on instrument platform• Clinical validation of test/s to ensure Dx accuracy for intended use (Se, Sp, PPV, NPV & Accuracy)
LDT initial commercialisation	<ul style="list-style-type: none">• Commercialise first as LDTs with CLIA certified laboratory partner/s in the US• Fast-to-market pathway enabling early revenues, access to 'real world' data (acceptable to FDA), build biobank & reimbursement case, and gain market acceptance
IVD regulatory authorisation	<ul style="list-style-type: none">• Gain IVD regulatory clearance/approval dependant on use (510k/De Novo/PMA submission)• Larger-scale, multi-site clinical studies to prove safety & efficacy in intended use population• Enables improved clinical adoption, reimbursement and partnering with Dx distributors
Expand indications & markets	<ul style="list-style-type: none">• Expand uses to BC and OC earlier detection in high-risk (&/or average-risk) asymptomatic women• Expand cancer applications to prostate, pancreatic & other cancers• Expand technology applications to improve specificity of CTC, PET & others• Expand regulatory approvals and market entry to EU, AU & Asia

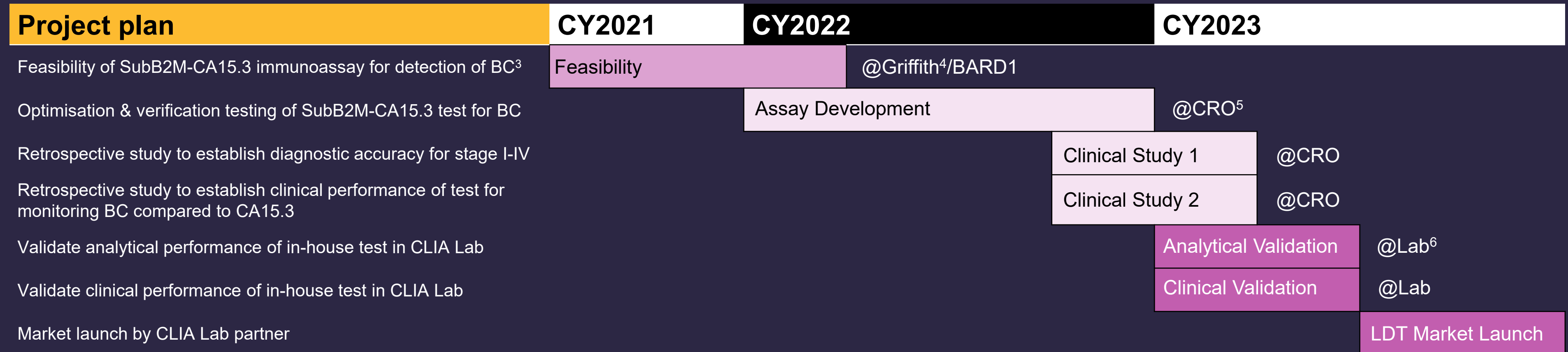
SubB2M | breast cancer test



Monitoring and detection of breast cancer

Data	<ul style="list-style-type: none"> POC study conducted by Griffith University to evaluate SubB2M SPR-based assay for detection of Neu5Gc in 118 samples of BC cases and controls >95% sensitivity and specificity for all stages of BC compared to controls^{1,2}
Next steps	<ul style="list-style-type: none"> Develop and validate SubB2M-CA15.3 immunoassay for monitoring BC Evaluate SubB2M-IHC for BC (Analyte Specific Reagent)

Stage	Breast Cancer ¹ n=118 (96 cancers : 22 controls)		
	Sensitivity	Specificity	AUC
Stage I	95.83%	100%	0.958
Stage II	100%	100%	1.000
Stage III	100%	100%	1.000
Stage IV	100%	100%	1.000



POC = Proof of Concept; SPR = Surface Plasmon Resonance; BC = Breast Cancer; AUC = Receiver Operating Characteristic Area Under the Curve;

¹ Pre-print manuscript <https://www.biorxiv.org/content/10.1101/2021.06.21.449179v2>; ² Samples provided by Victorian Cancer Biobank; ³ Awarded competitive BTB funding from MTPConnect to develop tests for monitoring & detection of BC; ⁴ Collaborative Research Agreement with the Institute for Glycomics at Griffith University; ⁵ Contract Research Organisation; ⁶ CLIA-certified high-complexity laboratory

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SubB2M | ovarian cancer test



Monitoring and detection of ovarian cancer

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Data	<ul style="list-style-type: none"> POC study conducted by Griffith University to evaluate SubB2M SPR-based assay for detection of Neu5Gc in 69 samples of OC cases and controls 100% sensitivity and specificity for all stages of OC compared to controls^{1,2}
Next steps	<ul style="list-style-type: none"> Develop and validate SubB2M-CA125 immunoassay for monitoring OC <ul style="list-style-type: none"> ✓ Initial POC achieved for SubB2M-CA125 ELISA-based test Evaluate SubB2M-IHC for OC (ASR)

Stage	Ovarian Cancer n=69 (47 cancers : 22 controls)		
	Sensitivity	Specificity	AUC
Stage I	100%	100%	1.000
Stage II	100%	100%	1.000
Stage III	100%	100%	1.000
Stage IV	100%	100%	1.000

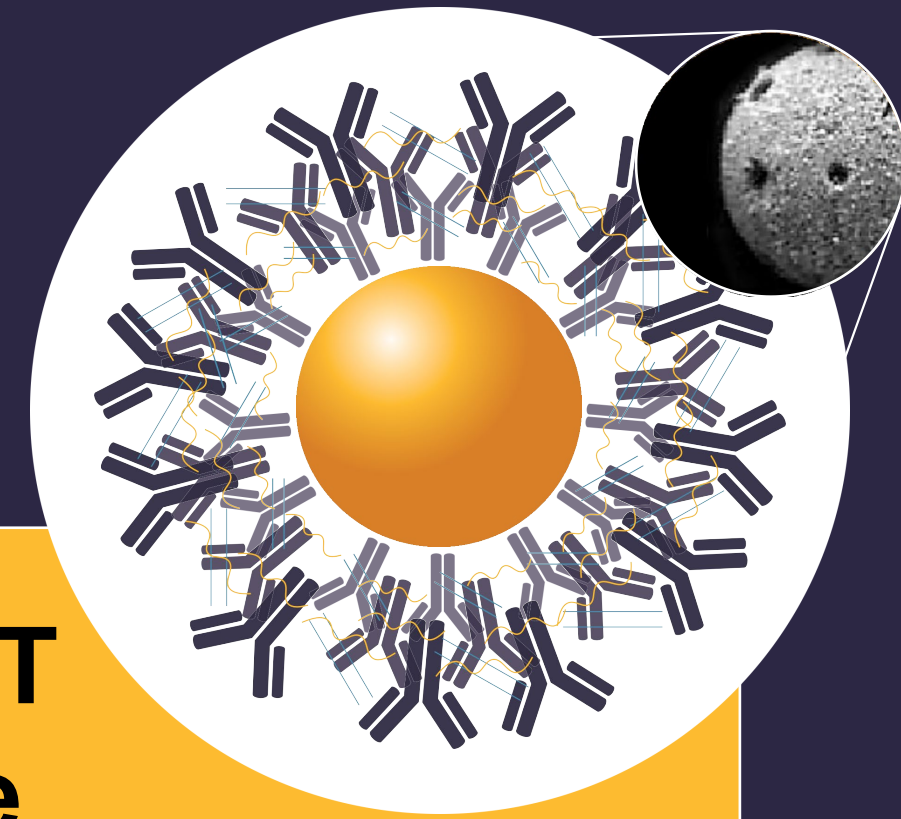


POC = Proof of Concept; SPR = Surface Plasmon Resonance; OC = Ovarian Cancer; AUC = Receiver Operating Characteristic Area Under the Curve;

¹ Pre-print manuscript available <https://www.biorxiv.org/content/10.1101/2021.06.21.449179v2>; ² Samples provided by Victorian Cancer Biobank; ³ Collaborative Research Agreement with the Institute for Glycomics at Griffith University; ⁴ Contract Research Organisation; ⁵ CLIA-certified high-complexity laboratory

EXO-NET | products & pipeline

Enabling technology for exosome research, diagnostic and therapeutic applications



RUO EXO-NET[®] product



- RUO EXO-NET is a **pan-exosome capture tool** for research use
- Suitable for enrichment from **blood, urine, saliva** and **cell culture**
- Highly scalable with **speed, purity and yield** advantages
- **Commercialisation strategy** to embed EXO-NET into the discovery, research & development phases of future **exosome-based Dx and Tx**
- **Evaluations** progressing with multiple KOLs in academia & industry
- Plans to expand **collaborations** with KOLs to validate use of EXO-NET in key exosome applications
- **Presentations** of research at scientific conferences
- **Publication** of in-house and collaborator data in peer reviewed journals to build product awareness, validate technology & gain adoption
- Secure **distributor/s** for RUO EXO-NET to manage distribution & sales
- Research market estimated at **US\$100-500m** by 2026¹

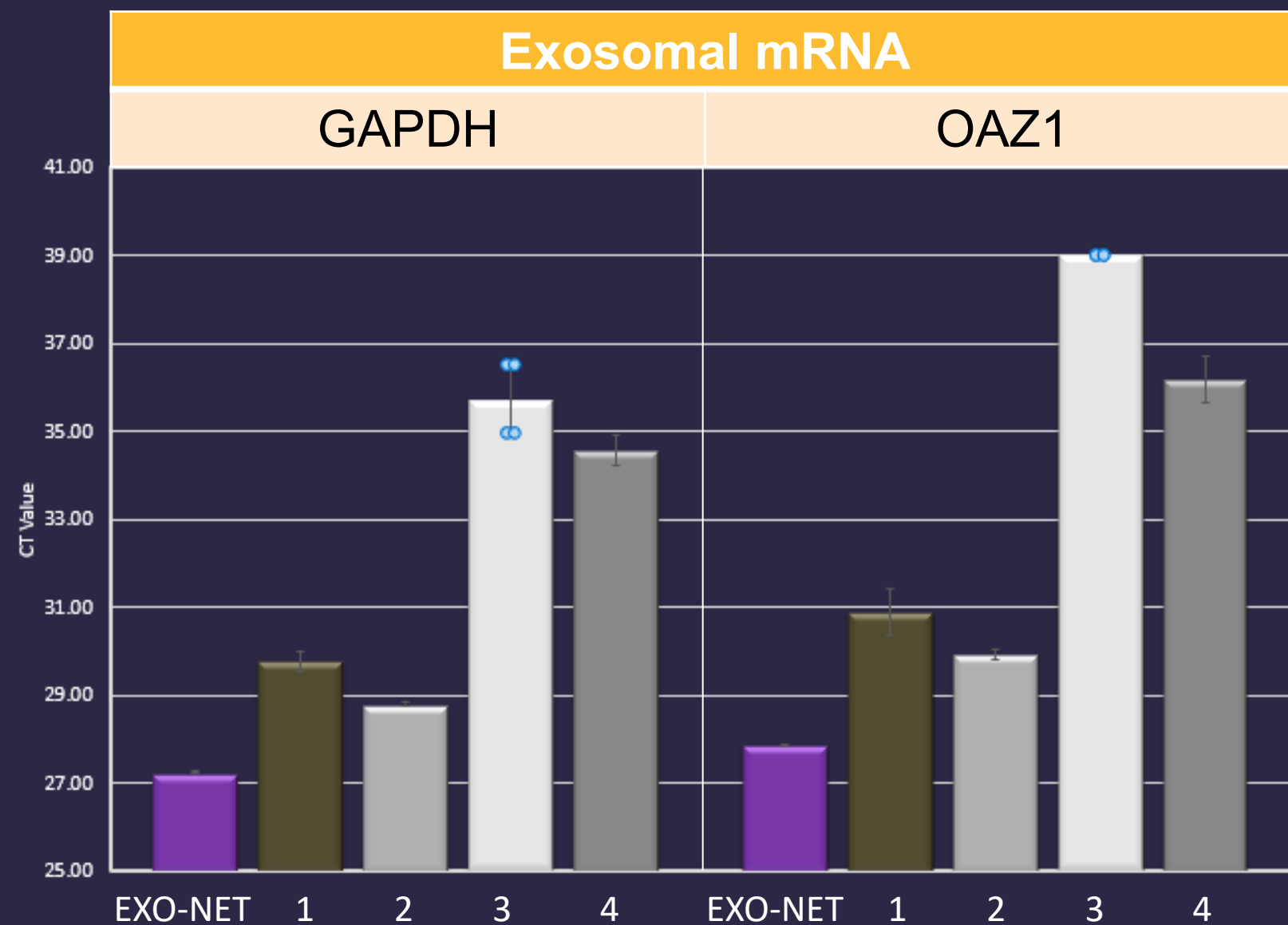
EXO-NET pipeline

- **EXO-NET** is a proprietary multi-layered matrix of capture antibodies coated onto magnetic beads to enable efficient exosome isolation
- **Exosomes** are nano-particles (30-150nm) produced by cells containing nucleic acids, proteins & lipids that are **biomarkers** for diagnosis and treatment of multiple diseases including cancer, metabolic, neurological
- New product opportunities:
 1. **IVD** EXO-NET for diagnostic use
 2. **Capture and release** EXO-NET for therapeutic applications
 3. **Customised** EXO-NETs for capture of specific exosomal targets
 4. In-house exosome-based **cancer diagnostics**
 5. Partnered exosome-based **companion diagnostics (CDx)**
- Potential for **contract research fees** and **license revenues** from upfront fees, development milestones & royalties
- Global exosomes market for Dx and Tx **US\$2.3b** by 2030²

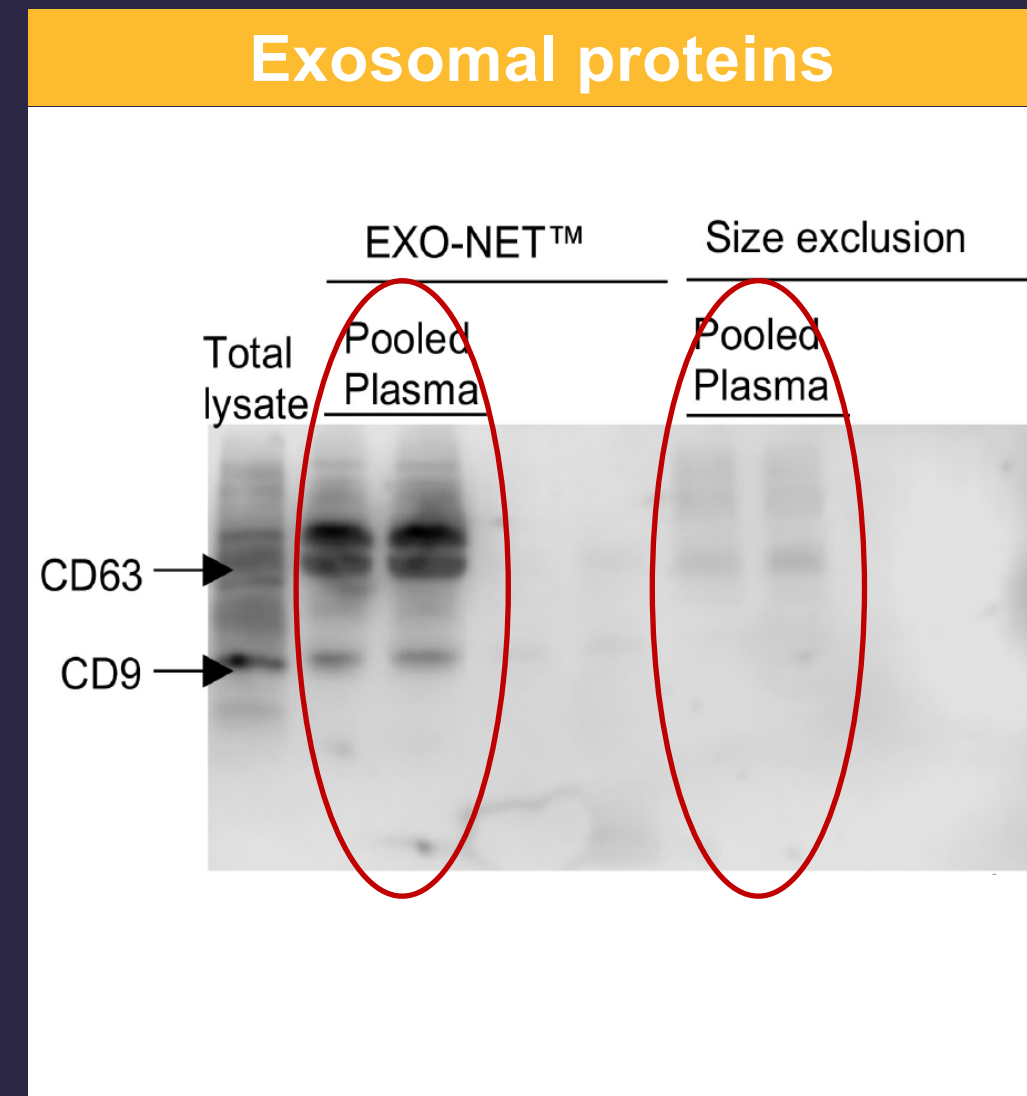
EXO-NET | comparison data

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- Scalable exosome isolation for high throughput screening
- Speed, purity and yield advantages
- Compatible with downstream exosomal RNA & protein analyses



EXO-NET results in higher recovery of exosomal mRNA compared to 4 commercial exosome isolation kits



EXO-NET results in enrichment of exosomal proteins compared to SEC

“EXO-NET enables simple and rapid exosome capture for clinical applications.”
BARD1 collaborator

BARD1 | technology and autoantibody tests



- Splice variants of **BARD1** are associated with cancer formation, progression and poor prognosis
- **BARD1 autoantibody (AAb) tests** measure autoantibodies to BARD1 variants and use a weighted algorithm to give a cancer score
- Potential applications for **earlier cancer detection** in high-risk individuals
- **POC studies**¹ performed at UNIGE² using a research-stage multi-peptide immunoassay on MSD platform³ showed high accuracy for detection of ovarian, breast & lung cancers compared to healthy controls
- 20-peptide assay developed under contract by Thermo Fisher Scientific on Luminex platform for commercialisation (prototype RUO BARD1 kit)
- Evaluations at UNIGE and Griffith confirmed assay performance, but further assay design, development and technical validation required before advancing to clinical development

Product	Study	n (cancer:normal)	AUC	Sensitivity	Specificity
BARD1 Ovarian	OC-CA125 (ave-risk)	400 (200:200)	0.95	88%	93%
	OC-R001 (high-risk)	261 (127:134)	0.97	89%	97%
BARD1 Breast	BC-001a (ave-risk)	123 (61:64)	0.86	70%	88%
	BC-001b (benign)	110 (61:49)	0.84	85%	76%
BARD1 Lung	LC-POC (ave-risk)	187 (94:93)	0.86	80%	77%

AUC is the accuracy of the test; Sensitivity is the % of people with cancer that correctly test positive; Specificity is the % people without cancer that correctly test negative.

¹ POC = Proof of concept; ² UNIGE = University of Geneva; ³ Meso Scale Discovery (MSD) immunoassay platform

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hTERT | ICC test for detection of hTERT

Anti-hTERT antibody

Anti-hTERT Antibody

- hTERT test is an immunocytochemistry (ICC) assay that **detects hTERT**
- **Adjunct to urine cytology** to assist bladder cancer diagnosis
- **Registered** in US (FDA Class I), Europe (CE-IVD mark), South Korea (MFDS Class II) & Australia (TGA Class II)
- **Distributors appointed** in US (StatLab), Greece (Aenoresis), Sweden (TrioLab), Israel (Zotal) & South Korea (Mirax)
- **US:** Generating ~A\$550k revenue pa & reimbursable US\$108 per test
- **ROW:** Initial commercialisation efforts focused on establishing test in Key User / reference laboratories; User pays
- **US bladder cancer market:** incidence 80,617, prevalence 269,259, 1.7m urine cytology tests pa on new cases of haematuria (2017)^{1,2}



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Catalysts

Expected value-adding milestones over the next 12 months

Key catalysts

- Further **feasibility results** for SubB2M immunoassay tests
- Appoint **CRO** to advance assay development
- Commence **clinical studies** for SubB2M **breast** and **ovarian cancer tests**
- Contract **manufacturing** agreements for reagents
- Secure **laboratory partner/s** for Dx commercialisation
- Appoint **distribution partner/s** for RUO EXO-NET
- Expand collaboration / **licensing opportunities** for EXO-NET

Summary

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Lifesciences company	<ul style="list-style-type: none">• Focused on unmet needs for earlier detection of cancer to save lives
Game changing technology	<ul style="list-style-type: none">• Proprietary technologies with clear advantages for multiple cancer applications
Strong pipeline	<ul style="list-style-type: none">• Multi-product pipeline for detection of common and deadly cancers
Compelling POC results	<ul style="list-style-type: none">• POC results for lead SubB2M tests show high sensitivity & specificity for detection of breast and ovarian cancers¹
Commercialised products	<ul style="list-style-type: none">• Products in-market for bladder cancer² and exosome research
Significant growth potential	<ul style="list-style-type: none">• Targeting unmet needs in US\$11b global markets
Experienced leadership	<ul style="list-style-type: none">• Track record in healthcare leadership, Dx development and commercialisation
Strong cash position	<ul style="list-style-type: none">• Cash balance of \$20.4m to fund development of lead diagnostics³

Contacts



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