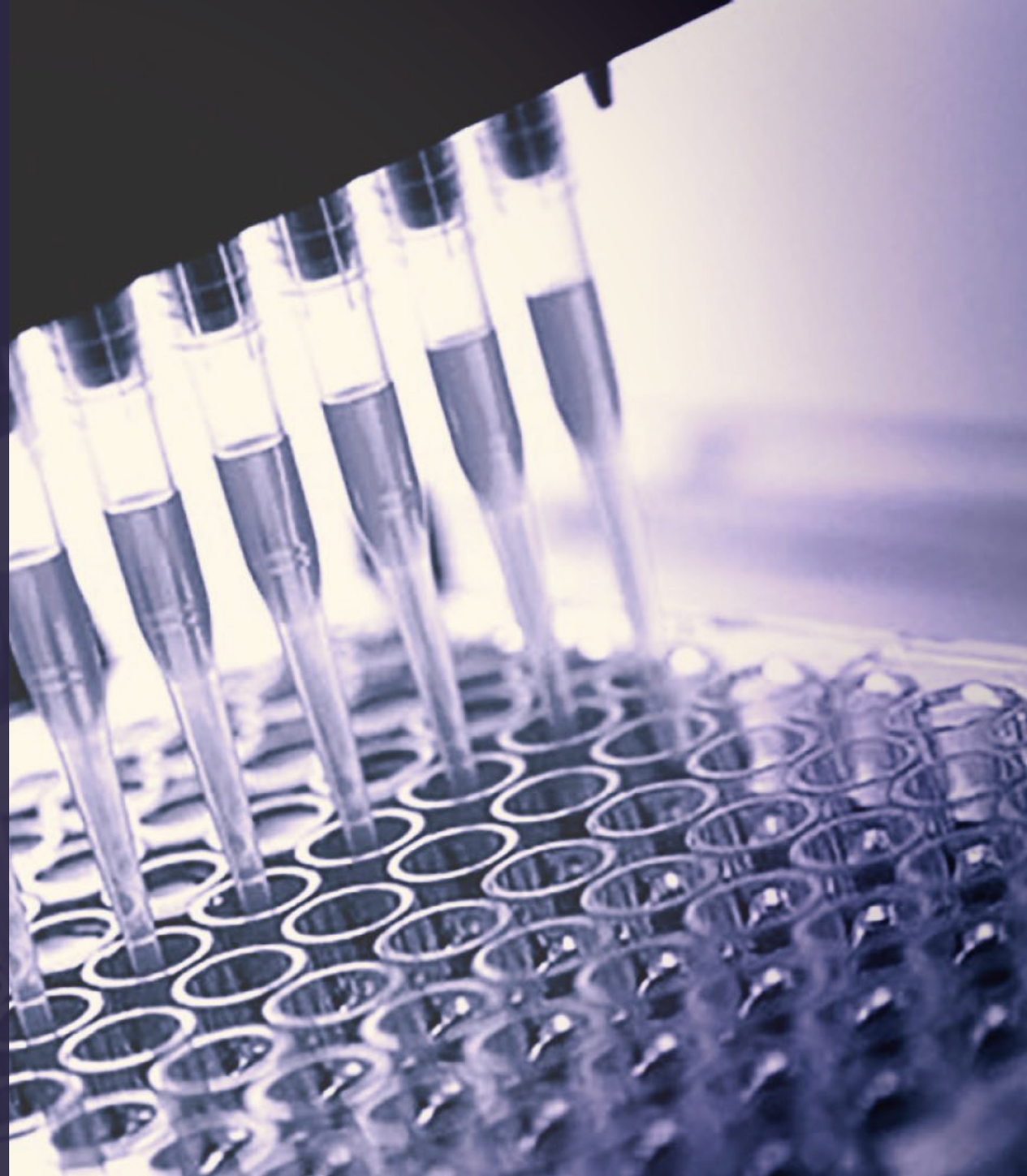
BARD1
LIFE SCIENCES LIMITED

Detecting cancer earlier to save lives

Annual General Meeting
29 November 2021

CEO Presentation



BARD1 Life Sciences Ltd (ASX:BD1)
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Company overview

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 cancers[1]
- Strong cash position to commercialise lead products as LDTs
- Products in-market for bladder cancer[2] & exosome research

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%

Board and management


Dr Geoff Cumming
Chairman


Max Johnston
Non-Exec Director


Phillip Powell
Non-Exec Director


Prof Allan Cripps
Non-Exec Director


Dr Leearne Hinch
Chief Executive Officer


Dr Greg Rice
Chief Scientific Officer

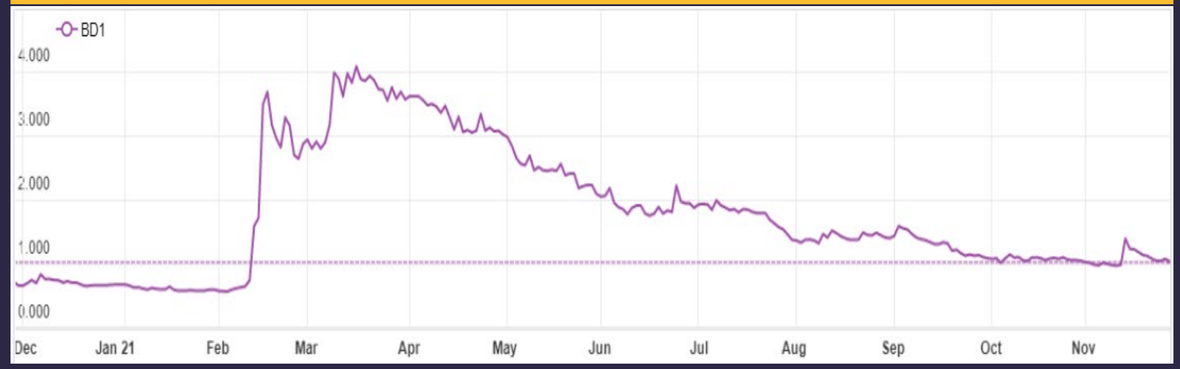

Tony Di Pietro
CFO / Company Sec


Susan Belzer
Development Director


Dr Wayne Jensen
R&D Director


Dr Emily Stein
Technology Director (NETs)

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

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

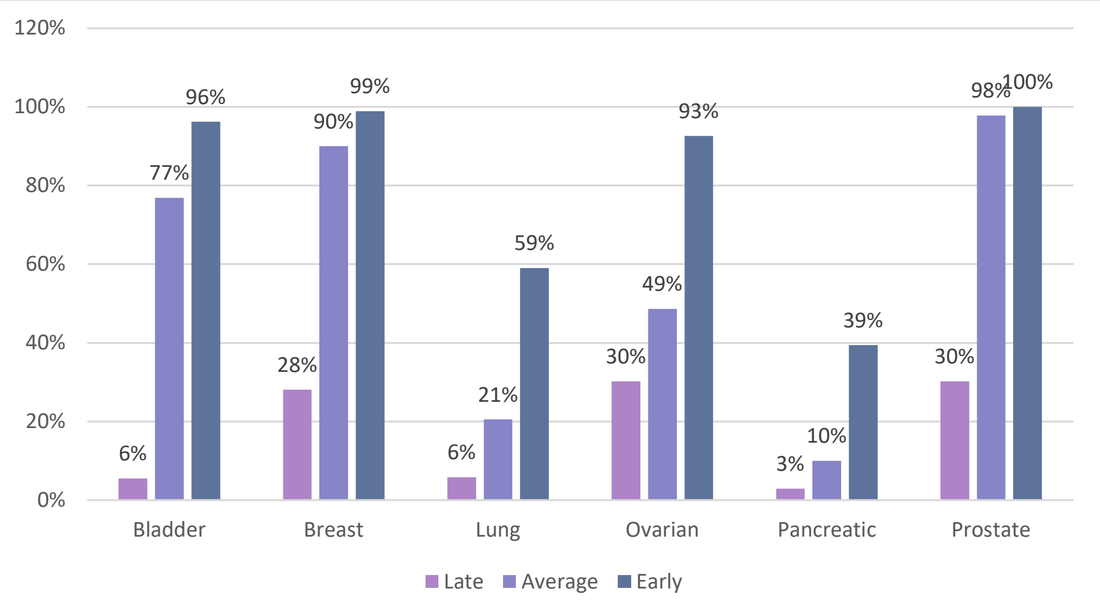
Problem

- 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 & survival[1]

5-year survival rates by stage at diagnosis[1]

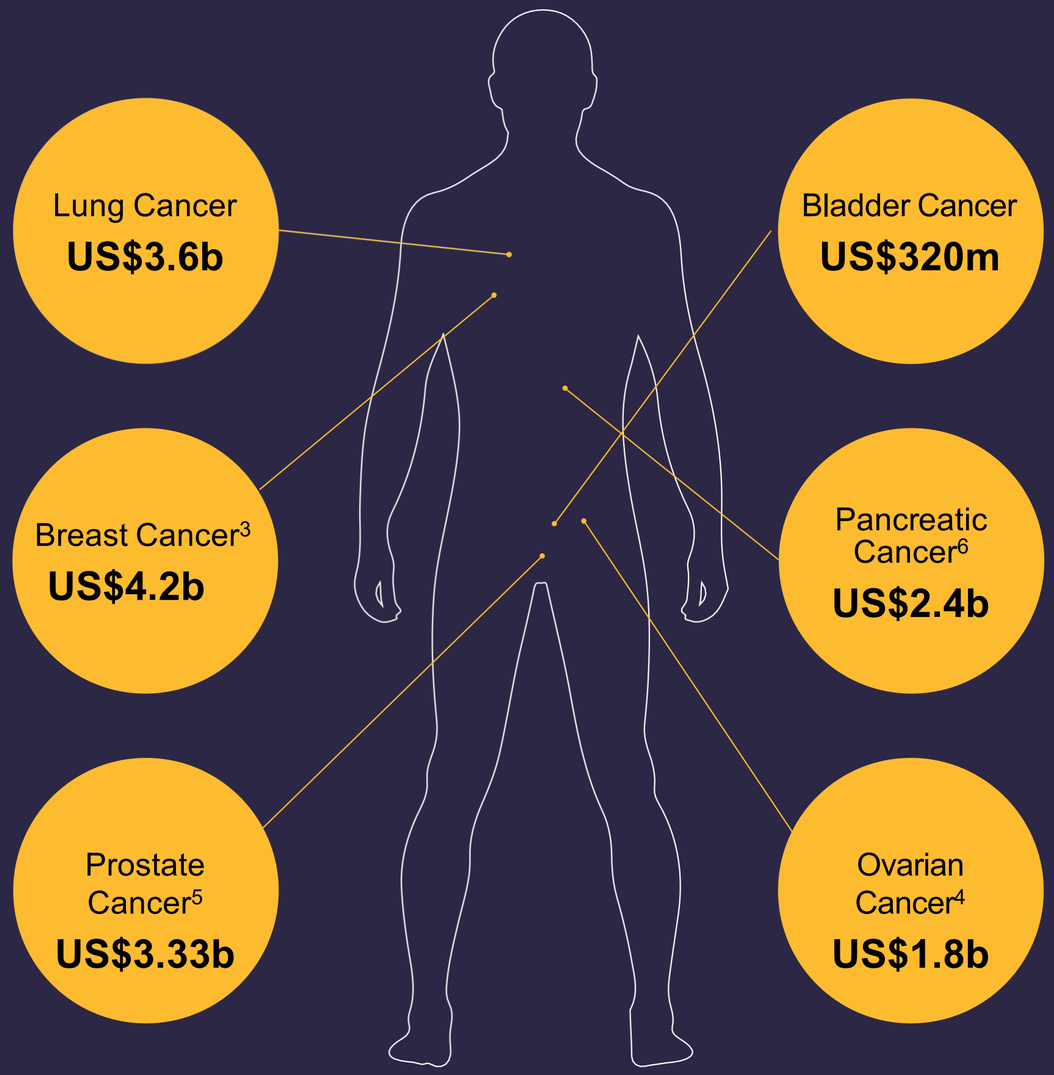


1 SEER 18 2010-2016

Global cancer diagnostics market

- Global cancer burden: 50.6m survivors, 19.3m new cases and 10.0m deaths p.a.[1]
- Global cancer diagnostics market valued at US$250b[2]
- 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



1 GLOBOCAN (IARC) 2020; 2 Grand View Research 2019. https://www.grandviewresearch.com/press-release/global-cancer-diagnostics-market; 3 https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market; 4 https://www.grandviewresearch.com/industry-analysis/ovarian-cancer-diagnostics-market; 5 https://www.grandviewresearch.com/industry-analysis/prostate-cancer-diagnostics-market; 6 https://www.wboc.com/story/43615802/pancreatic-cancer-diagnostic-market-size-2021-with-a-cagr-of-69-top-companies-data-report-covers-market-specific-challenges-brief-analysis-and

Breast cancer | US screening market potential

- World's most common cancer: 2.3m new cases & 685k deaths pa[1]
- 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* mutations [2]
- Screening using mammography recommended for average-risk women and those with a family history or genetic mutations[3]
- 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]

Indicative Price \ Market Penetration	US Breast Cancer Market pa (USD) 10%	20%	30%
$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: biennial[4]
- Price: indicative pricing only[5]

QOL = Quality of Life; 1 Cancer Today 2020 data; 2 SEER 18 2011-2017 https://seer.cancer.gov/statfacts/html/breast.html; 3 US Census. International Data Base (IDB). 2021. https://www.census.gov/data-tools/demo/idb/#/country?YR_ANIM=2021&FIPS_SINGLE=US&dashPages=BYAGE&ageGroup=5Y; 4 ACS 2021 https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html; 5 This is not a sales forecast.

Ovarian cancer | US screening market potential

- World's deadliest gynaecological cancer: 314k new cases & 207k deaths pa[1]
- 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 women[4]
- 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]

	Market Penetration	US Ovarian Cancer Market pa (USD)		
		10%	20%	30%
Indicative Price	$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 years[3]
- Screening frequency: annual
- Price: indicative pricing only[5]

QOL = Quality of Life; TVUS = Transvaginal Ultrasound; OC = Ovarian cancer; 1 Cancer Today 2020 data; 2 SEER 18 2011-2017 https://seer.cancer.gov/statfacts/html/ovary.html; 3 US Census. International Data Base (IDB). 2021. https://www.census.gov/data-tools/demo/idb/#/country?YR_ANIM=2021&FIPS_SINGLE=US&dashPages=BYAGE&ageGroup=5Y; 4 ACS 2021 https://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/detection.html; 5 This is not a sales forecast.

Product and pipeline portfolio

- Commercial products for bladder cancer[1] & 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	→	→		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	→			

LEAD PIPELINE PRODUCTS

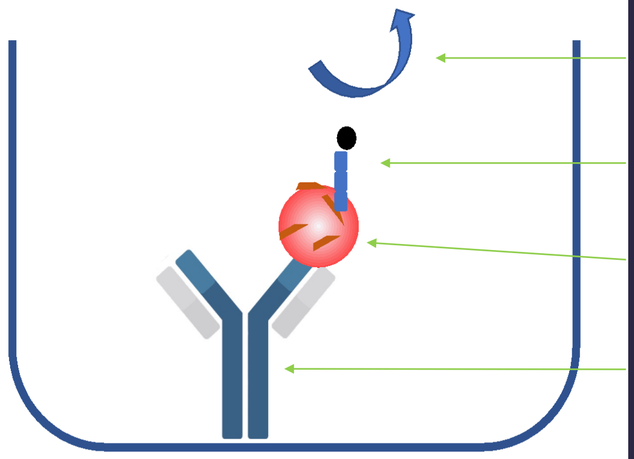
RUO = Research Use Only; **Dates will be released when projects are further advanced; ICC = Immunocytochemistry;
1 Adjunct to urine cytology to assist the detection of bladder cancer; 2 Progression subject to further assay design, development & validation

SubB2M™ | technology and test method

Game-changing technology for monitoring and detection of cancer

- SubB2M protein detects a unique cancer marker Neu5Gc found in human cancer tissues, cells & biofluids[1]
- Exclusive worldwide licence to SubB2M technology for diagnostic applications[2]
- 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

SubB2M immunoassay



1 Neu5Gc is not expressed in normal human tissue; 2 License from University of Adelaide and Griffith University; 3 Shewell et al. *N-glycolylneuraminic acid serum biomarker levels are elevated in breast cancer patients at all stages of disease*". 2021: https://www.biorxiv.org/content/10.1101/2021.06.21.449179v2 ; HRP = Horseradish Peroxidase

Commercialisation | goals and strategy

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

Develop SubB2M-based immunoassay	• 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	• 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 commercial-isation	• 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	• 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	• 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**

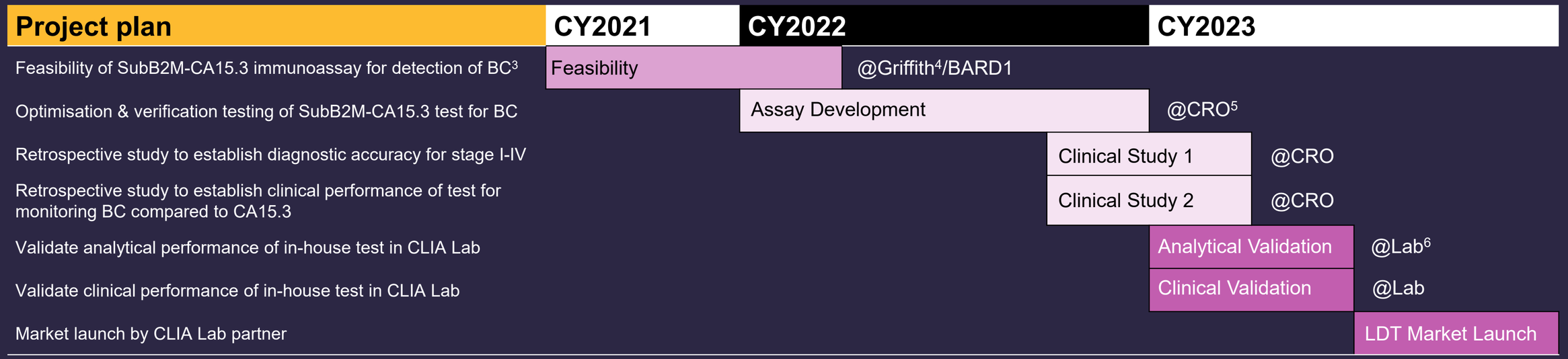
ELISA = Enzyme Linked Immunosorbent Assay; LDT = Laboratory Developed Test; CLIA = Clinical Laboratory Improvement Amendment;; IVD = In Vitro Diagnostic; FDA = US Food and Drug Administration; BC = Breast Cancer; OC = Ovarian Cancer; CTC = Circulating Tumour Cell; PET = Position Emission Tomography

SubB2M | breast cancer test

Monitoring and detection of breast cancer

Data	• 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	• 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



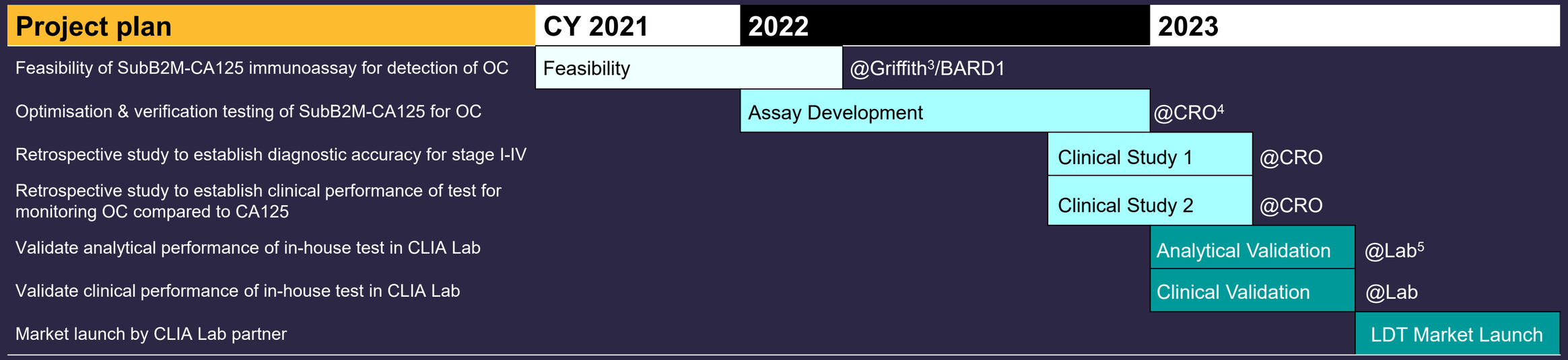
POC = Proof of Concept; SPR = Surface Plasmon Resonance; BC = Breast Cancer; AUC = Receiver Operating Characteristic Area Under the Curve;
1 Pre-print manuscript https://www.biorxiv.org/content/10.1101/2021.06.21.449179v2; 2 Samples provided by Victorian Cancer Biobank; 3 Awarded competitive BTB funding 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

SubB2M | ovarian cancer test

Monitoring and detection of ovarian cancer

Data	• 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	• Develop and validate SubB2M-CA125 immunoassay for **monitoring OC** ✓ Initial POC achieved for SubB2M-CA125 ELISA-based test • Evaluate SubB2M-IHC for OC (ASR)

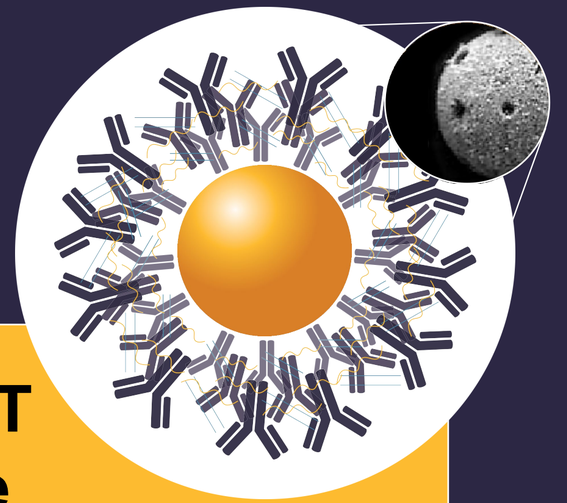
Stage	Ovarian Cancer n=69 (47 cancers : 22 controls)		
	Sensitivity	Specificity	AUC
Stage I	100%	100%	1.000
Stage II	100%	100%	1.000
Stage III	100%	100%	1.000
Stage IV	100%	100%	1.000



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 2026[1]

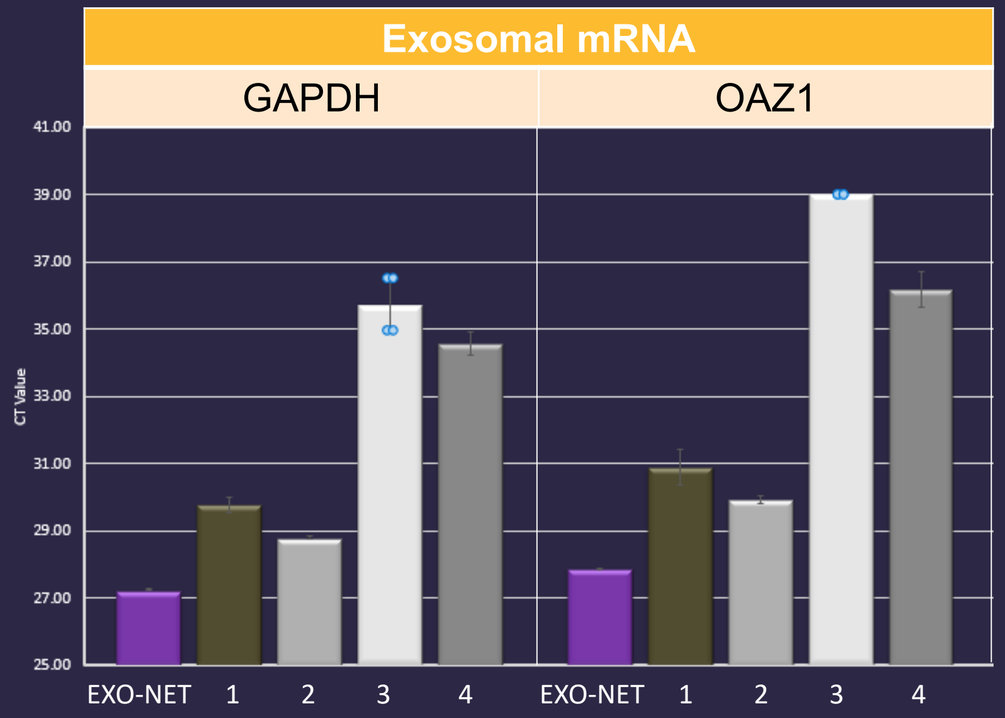
EXO-NET pipeline

- **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 2030[2]

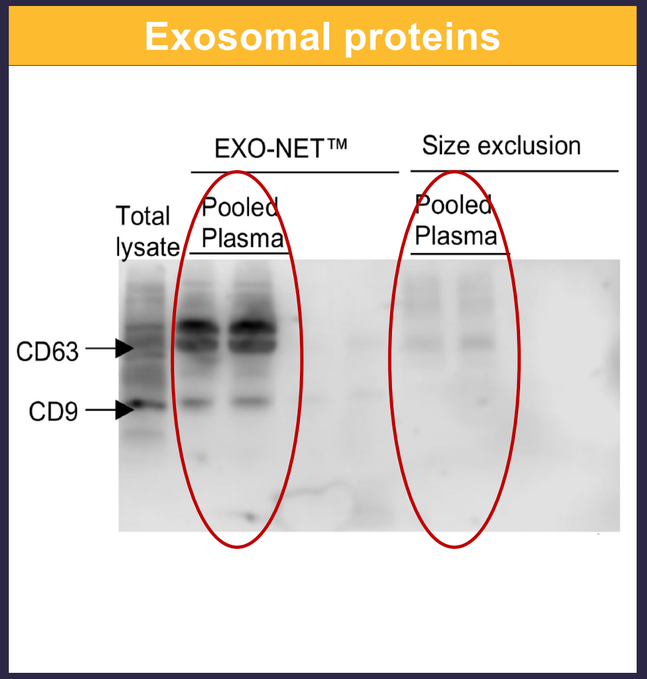
RUO = Research Use Only; KOLs = Key Opinion Leaders; Dx = Diagnostics: Tx = Therapeutics
1 BARD1 estimate; 2 Grand View Research 2018

EXO-NET | comparison data

- 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 UNIGE[2] using a research-stage multi-peptide immunoassay on MSD platform[3] 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

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]

1 Cancer Today (IARC) 2020; 2 Pacific Edge Annual Report 2019

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

Milestones and timelines subject to change based on results, sample access, partner/regulatory engagement; impact of COVID-19 delays, and other factors outside of management control

Summary

Lifesciences company	• Focused on unmet needs for earlier detection of cancer to save lives
Game changing technology	• Proprietary technologies with clear advantages for multiple cancer applications
Strong pipeline	• Multi-product pipeline for detection of common and deadly cancers
Compelling POC results	• POC results for lead SubB2M tests show high sensitivity & specificity for detection of breast and ovarian cancers[1]
Commercialised products	• Products in-market for bladder cancer[2] and exosome research
Significant growth potential	• Targeting unmet needs in US$11b global markets
Experienced leadership	• Track record in healthcare leadership, Dx development and commercialisation
Strong cash position	• Cash balance of $20.4m to fund development of lead diagnostics[3]

Dx = Diagnostics; 1 SubB2M proof-of-concept data; 2 Adjunct to urine cytology to assist the detection of bladder cancer; 3 As at 30 Sep 2021

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