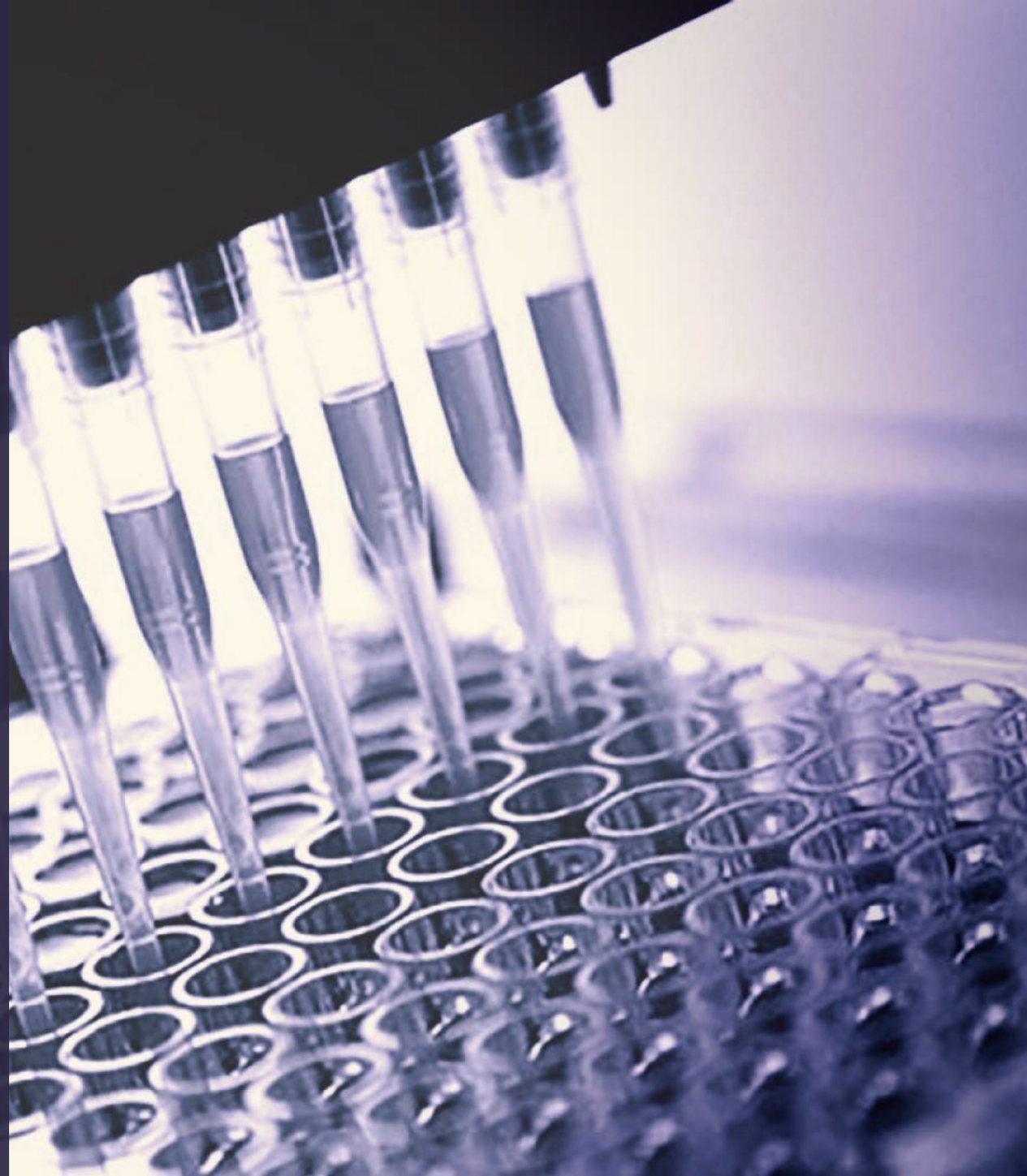
BARD1
LIFE SCIENCES LIMITED

Detecting cancer earlier to save lives

Bell Potter Healthcare Conference
10 November 2021

Leearne Hinch | CEO



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Company overview

BARD1 Life Sciences (ASX: BD1)

- Diagnostics company focused on earlier detection of cancer
- Game-changing technologies with multiple applications
- Strong pipeline for breast, ovarian, prostate & other cancer diagnostics 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

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


Dr Wayne Jensen
R&D Director


Dr Emily Stein
Technology Director (NETs)

BARD1 History

2016	BARD1 AAb technology acquired
2020	SubB2M and EXO-NET® technologies acquired / in-licensed
2021	SubB2M proof-of-concept results for breast and ovarian cancers
	RUO EXO-NET exosome capture tool launched

Financial information (ASX:BD1)	
Ordinary shares	91,934,920
Share price (9/11/21)	A$0.985
Market capitalisation	A$90.6m
Cash position (30/9/21)	A$20.4m
Ave monthly cash burn (Q1 FY22)	A$593k

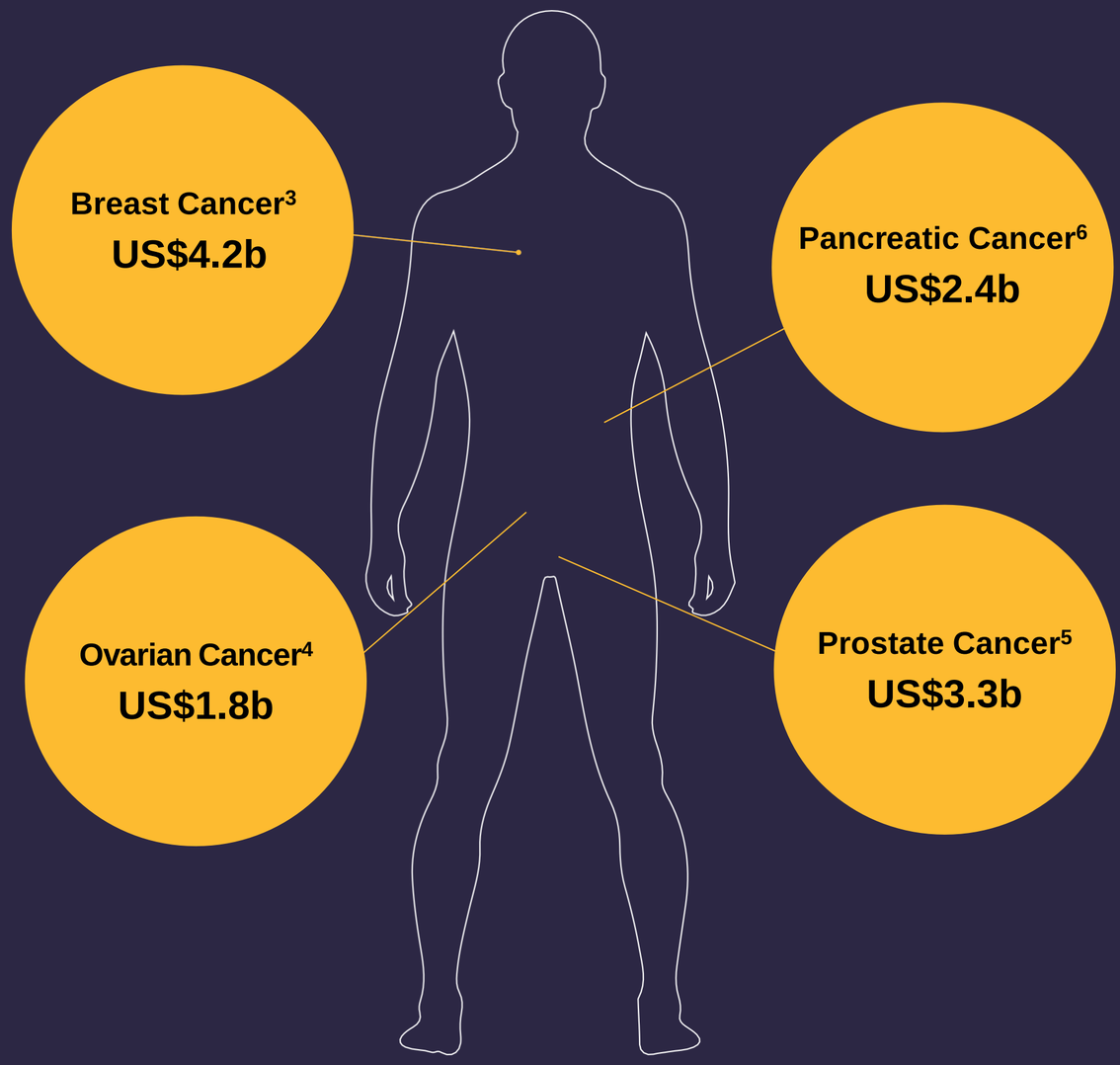
Share price performance (Past 12 months)

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

Global cancer diagnostics market

- Global cancer burden: 50.6m people, 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 US$11b for some of the world's most common and deadliest cancers

#	Cancer	Prevalence	Incidence	Deaths
1	Breast [1]	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

Unmet need for earlier cancer detection

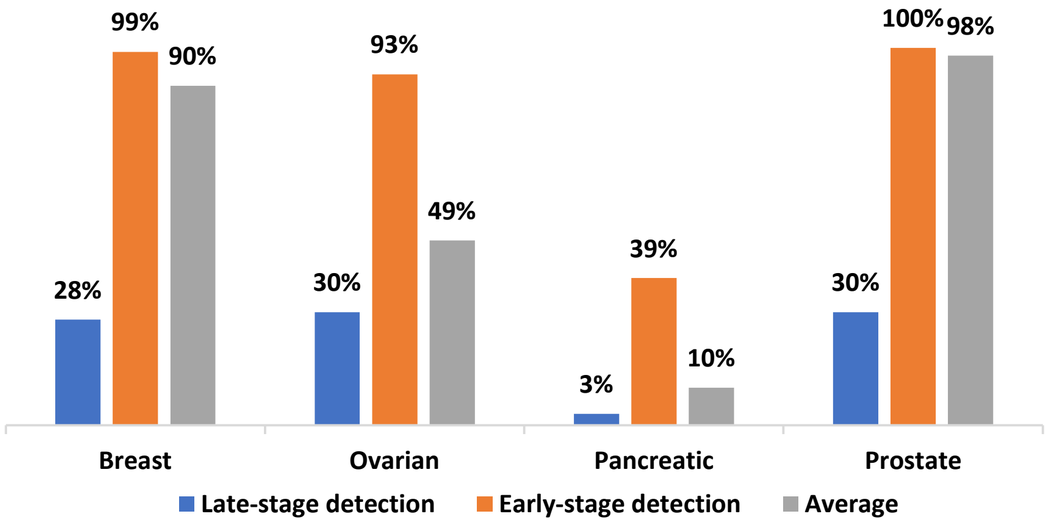
The problem

- 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]

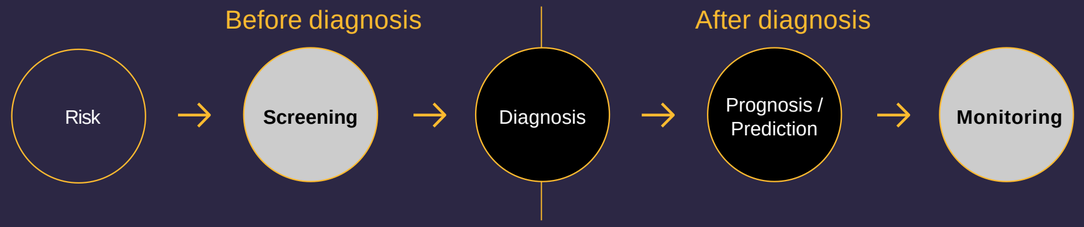
5-year survival rates by stage at diagnosis[1]



1 SEER 18 2010-2016

Product and pipeline portfolio

- Commercial products for bladder cancer[1] & exosome research
- Lead pipeline products for breast & ovarian cancer
- Focused on earlier detection & monitoring of 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	→			

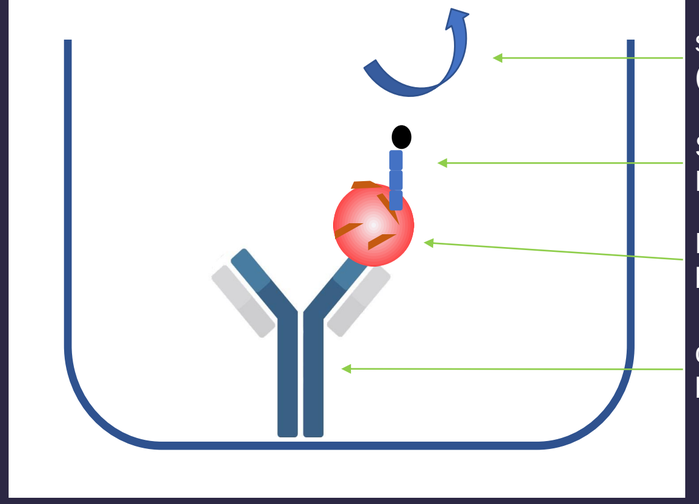
*RUO = Research Use Only; **Dates will be released when projects are further advanced; ICC = Immunocytchemistry;
1 Adjunct to urine cytology to assist the detection of bladder cancer; 2 Progression subject to outcome of BARD1-Ovarian results

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

SubB2M | 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 tests for **monitoring breast and ovarian c**ancers on platform compatible with high-throughput laboratory workflow
Advance lead Dx pipeline	• **Preclinical 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 commercial-isation	• Commercialise first as **LDTs by 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 wider clinical adoption, market access and reimbursement of kit
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

Breast cancer | US 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: 10%	20%	30%
	US Breast Cancer Market pa (USD)		
$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]

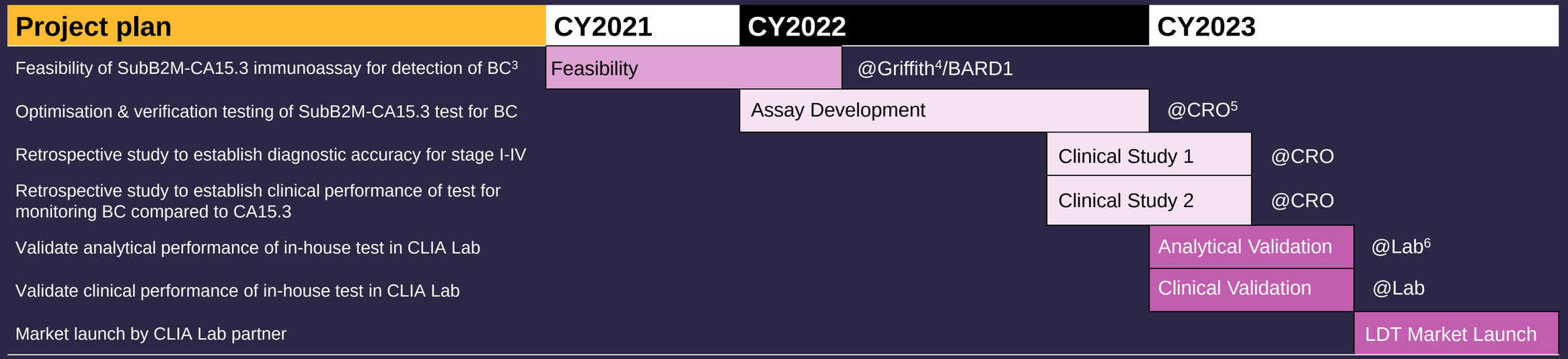
QOL = Quality of Life; 1 Cancer Today 2020 data; 2 SEER 18 2011-2017 https://seer.cancer.gov/statfacts/html/breast.html; 3 US Census. International Data Base (IDB). 2021. https://www.census.gov/data-tools/demo/idb/#/country?YR_ANIM=2021&FIPS_SINGLE=US&dashPages=BYAGE&ageGroup=5Y; 4 ACS 2021 https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-de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

SubB2M | breast cancer test

Monitoring and detection of breast cancer

Study	• POC study conducted by Griffith University to evaluate SubB2M SPR-based assay for detection of Neu5Gc in 118 samples of BC cases and controls
Results*	• >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

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

Ovarian cancer | US 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]

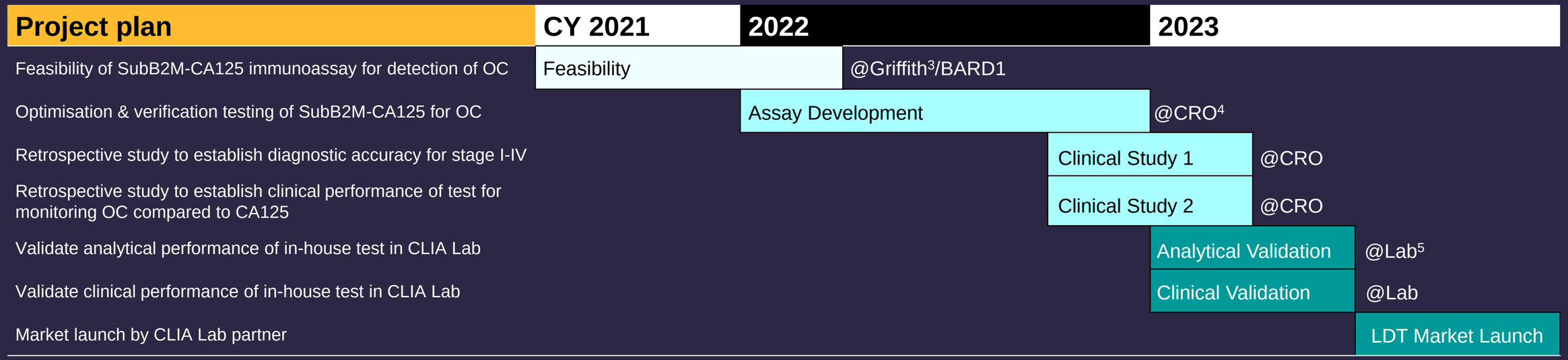
QOL = Quality of Life; TVUS = Transvaginal Ultrasound; OC = Ovarian cancer; 1 Cancer Today 2020 data; 2 SEER 18 2011-2017 https://seer.cancer.gov/statfacts/html/ovary.html; 3 US Census. International Data Base (IDB). 2021. https://www.census.gov/data-tools/demo/idb/#/country?YR_ANIM=2021&FIPS_SINGLE=US&dashPages=BYAGE&ageGroup=5Y;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

SubB2M | ovarian cancer test

Monitoring and detection of ovarian cancer

Study	• POC study conducted by Griffith University to evaluate SubB2M SPR-based assay for detection of Neu5Gc in 69 samples of OC cases and controls
Results*	• 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 feasibility achieved for SubB2M-CA125 ELISA-based test

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

Other research projects

Additional research projects are being evaluated for other cancers and indications for use

EXO-NET® technology projects

- EXO-NET technology is an **exosome isolation tool**
- **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
- Product opportunities:
  - ➢Customised **EXO-NETs** for capture and/or release of exosomes for diagnostic or therapeutic applications
  - ➢Exosome-based **cancer diagnostics**[1]
  - ➢Exosome-based **companion diagnostics (CDx)**
- Global exosomes market for Dx and Tx US$2.3b by 2030[2]

BARD1 technology projects

- BARD1 technology **detects autoantibodies to variant BARD1 proteins** associated with cancer formation, progression and poor prognosis
- Potential applications for **earlier cancer detection**
- **POC studies** performed at UNIGE[3] using a research-stage multi-peptide ELISA showed high accuracy for detection of ovarian, breast & lung cancers compared to healthy controls
- Further assay design, development and validation is required before advancing to clinical development[4]

1 Liquid biopsies to replace tissue biopsies; 2 Grand View Research 2018; 3 UNIGE = University of Geneva; 4 Further assay design, development and validation is required before advancing to clinical development

Products

Two products in-market for use in 1) exosome research, and 2) detection of hTERT

RUO EXO-NET®

- RUO EXO-NET is a **pan-exosome capture tool for** research use
- Suitable for enrichment in **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 results 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]

Anti-hTERT Antibody

- hTERT test is an immunocytochemistry (ICC) assay that detects hTERT and is used as an **adjunct to urine cytology to assist bladder cancer diagnosis**
- **Registered** in US (FDA Class I), Europe (CE Mark), South Korea (MFDS Class II) & Australia (TGA listed)
- **Distributors appointed** in US, Europe (Greece, Sweden, Israel) & Asia (South Korea)
- **US**: Generating $550k revenue pa & reimbursable
- **ROW**: Initial commercialisation efforts focused on establishing test in Key User / reference laboratories
- **Bladder cancer stats**: incidence 80,617, prevalence 269,259, **3.4m urine cytology tests pa** on new cases of haematuria in US[2,3]

RUO = Research Use Only; KOLs = Key Opinion Leaders; Dx = Diagnostics: Tx = Therapeutics
1 BARD1 estimate; 2 Cancer Today (IARC) 2020; 3 Pacific Edge Annual Report 2019

Achievements and Catalysts

Expected value-adding milestones over the next 12 months

Achievements Q1 FY22

- **hTERT** receipts of $221k (Q4 FY21: $184k)
- POC achieved **for SubB2M-CA125** test for OC
- UQ collaborator released promising **exosome-based OC test** data using EXO-NET for exosome capture (Jul-21)
- **Dr Greg Rice** PhD appointed CSO (Sep-21)
- Completed **capital raising of $18.4m** (Jul/Aug-21)
- **Cash position of $20.4m** at 30/9/21

Key catalysts next 12mo

- **Feasibility results** for SubB2M 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

Cancer diagnostics 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 BC & OC[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

Contacts

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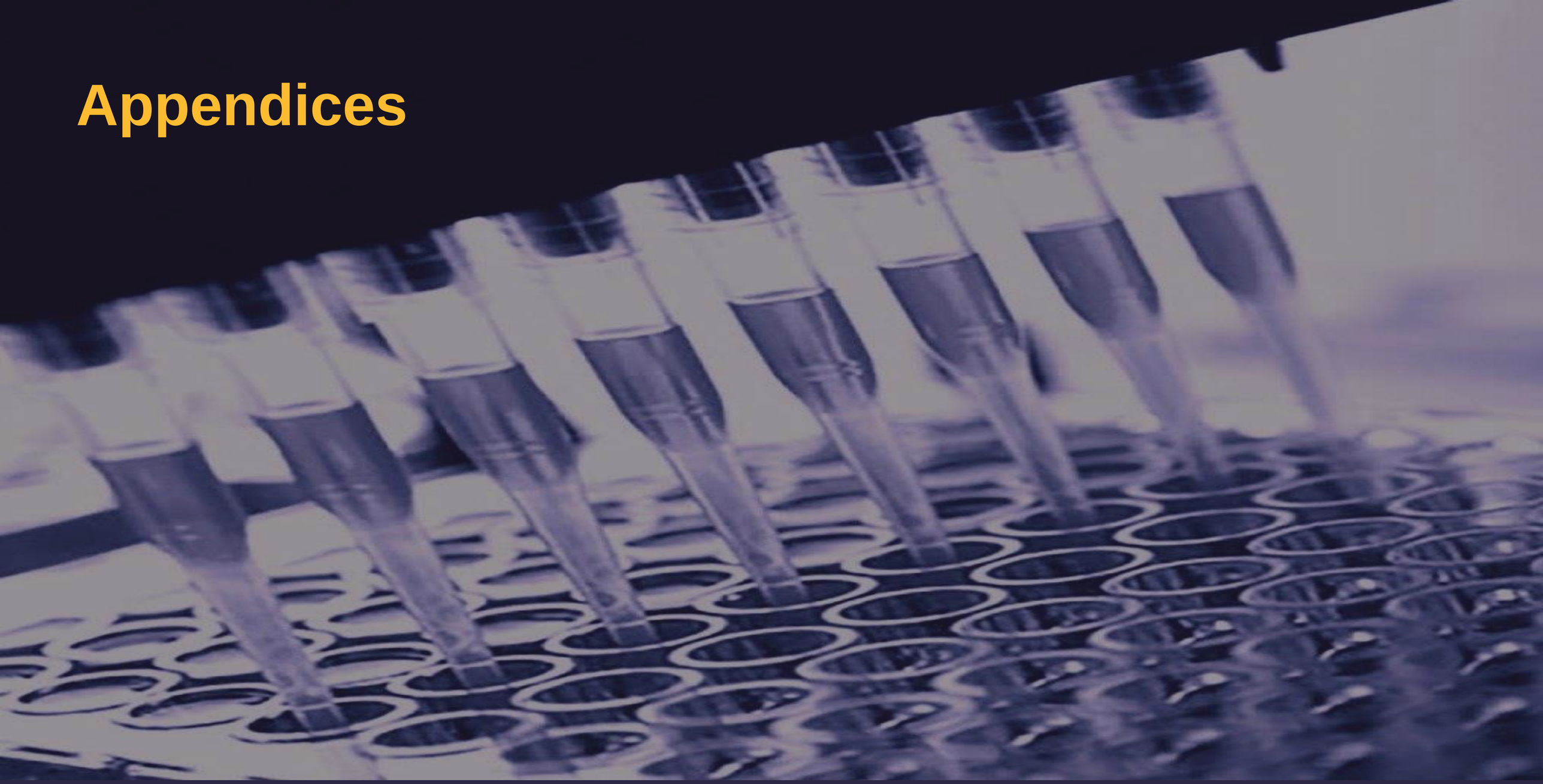
Appendices



Healthcare experienced board

DR GEOFF CUMMING PhD

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.
- Currently Chairman AusCann Group Holdings Ltd and NED of Medical Developments International 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, Arthur Andersen & NED Medical Developments International Ltd.
- Currently NED RMA Global Ltd.

Prof ALLAN CRIPPS AO PhD

Non-Executive Director

- Distinguished academic, clinical scientist and health services leader, having made significant contributions in immunology, diagnostics and health services.
- Previously Pro Vice Chancellor (Health) at Griffith University.
- Currently Professor Emeritus at Griffith University, leading the Mucosal Immunology Research Group (MIRG) and NED of Neurotech International Ltd.

Management with biotech track record

DR LEEARNE HINCH

Chief Executive Officer

- Dr Leearne Hinch BSc BVMS MBA is an experienced biotechnology executive and life sciences commercialisation consultant.
- Strong track record in company leadership, business strategy, operational management, fundraising, sales, business development and technology commercialisation.
- Previous senior executive and consulting roles in ASX-listed biotechnology, multi-national and private companies across diagnostics, devices, therapeutics and animal health.

DR GREG RICE PhD

Chief Scientific Officer

- Dr Greg Rice BSc PhD MHA GradDipMgt is an internationally recognised scientist with over 30 years' expertise and experience in oncology, perinatology, exosome-based research, clinical translational research, IVD development and commercialistion.
- Successful track record in oncology research, biomarker trials and diagnostics commercialisation.
- Previous leadership roles in academia and industry including UQ, Baker Heart Inst., UoM, Monash & HealthLinx.

DR WAYNE JENSEN PhD

R&D Director

- Dr Wayne Jensen PhD is an experienced medtech executive with extensive product development experience.
- Strong track record in product development from concept to commercialisation, having successfully brought 25 products to market including IVDs.
- Previous senior R&D, QA and consulting roles in medtech and diagnostics.

DR EMILY STEIN PhD

Technology Director (NETs)

- Dr Emily Stein PhD is an experienced life sciences executive and scientist, and is inventor of the NET technology.
- Strong track record in creating patented technologies and translating innovations from idea to commercialised products, with expertise in microbiology, rheumatology immunology and neurology.
- Previous leadership roles as founder and scientist in US-based life science start-ups.

TONY DI PIETRO

CFO & Company Secretary

- Tony Di Pietro BComm CA AGIA MAICD is a Chartered Accountant with strong corporate accounting experience, gained in Australia and the UK.
- Graduate Diploma of Applied Corporate Governance from the Governance Institute of Australia and member of the Australian Institute of Company Directors.
- Previous senior roles in ASX-listed biotechnology companies including Acrux Ltd.

Strong patent portfolio

- Broad patent portfolio covering BD1's core technologies and products
- Exclusive IP ownership / licensing
- 34 granted patents, 21 pending and 2 new provisional patent applications (at 3/11/21)
- Covers key jurisdictions (including US, Europe, Asia & Australia)

Patent Family	Title	Granted	Pending	Expiry
SubB2M				
PCT/AU2017/051230 (WO 2018/085888)	Subtilase cytotoxin B subunit mutant		AU, BR, CA, CN, EP, IN, JP, KR, US	2037
APPA/2021901444	Methods of analysing a sample			2042
BARD1				
PCT/FR01/02731 (WO/2002/018536)	Truncated BARD1 protein, and its diagnostic and therapeutic uses	US		2024
PCT/IB2011/053635 (WO/2012/023112)	BARD1 isoforms in lung and colorectal cancer and use thereof	AU, CA, CN, EP, HK, IL, JP, JP(div), US,SG, US(cont)	BR	2031
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 US(cont) 2032
PCT/EP2014/073834 (WO/2015/067666)	Lung Cancer Diagnosis	AU, IL, JP, SG, KR	CA, CN, EP, HK, US	2034
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, JP, IL, US	US (cont)	2035
PCT/AU2016/050764 (WO2017/027928)	Method of detecting cancer in morphologically normal cells	JP	US	2036
Molecular NETs				
PCT/US2010/058086 (WO2011/066449)	Devices for detection of analytes	CN, US, US (cont1), US cont2)	US (cont4)	2030 US 2032 US(cont1&2) 2031
PCT/US2013/049779 (WO2014/011673)	Molecular Nets	EP		2033
PCT/US2014/029823 (WO2014/153262)	Molecular nets on solid phases	AU, CN	CA, CN (div)	2034
APPA/2021901358 APPA/2021901359	Methods relating to tumour-derived extracellular vesicles			2042

cont = continuation; div = divsional