



## **Detecting cancer earlier to save lives**

Capital Raising Investor Presentation  
July 2021



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# Executive summary

Cancer diagnostics company	<ul style="list-style-type: none"><li>• Focused on early cancer detection to save lives</li></ul>
Game changing technology	<ul style="list-style-type: none"><li>• Patented technologies with clear advantages for multiple cancer applications</li></ul>
Compelling results	<ul style="list-style-type: none"><li>• &gt;95% sensitivity &amp; 100% specificity for detection of breast and ovarian cancers<sup>1</sup></li></ul>
Strong pipeline	<ul style="list-style-type: none"><li>• Pipeline for detection of common and deadly cancers</li></ul>
Commercialised products	<ul style="list-style-type: none"><li>• Products for bladder cancer<sup>2</sup> and exosome research</li></ul>
Significant growth potential	<ul style="list-style-type: none"><li>• Targeting unmet needs in US\$11b global markets</li></ul>
Experienced leadership	<ul style="list-style-type: none"><li>• Track record in healthcare leadership, Dx development and commercialisation</li></ul>
Capital Raising	<ul style="list-style-type: none"><li>• BARD1 has raised \$15m via a placement to sophisticated and professional investors to be followed by an SPP on the same terms to raise up to \$2m<sup>1</sup></li></ul>

<sup>1</sup>The BD1 Board reserves the right to scale back, close early and accept oversubscriptions under the SPP

Dx = Diagnostics; <sup>1</sup> SubB2M proof-of-concept data; <sup>2</sup> Adjunct to urine cytology to assist the detection of bladder cancer

# Company overview

## BARD1 Life Sciences (ASX: BD1)

- Diagnostics company focused on early cancer detection
- Game-changing technology with multiple applications
- Dx pipeline for breast, ovarian, prostate & pancreatic cancers targeting US\$11b global markets
- Lead products >95% se & 100% sp for all stages of breast & ovarian cancer
- GTM in partnership with clinical laboratories and diagnostics distributors
- Commercialised products for bladder cancer & exosome research

## Board and management

	<b>Dr Geoff Cumming</b> Chairman		<b>Dr Leearne Hinch</b> Chief Executive Officer
	<b>Max Johnston</b> Non-Exec Director		<b>Dr Peter French</b> Chief Scientific Officer
	<b>Phillip Powell</b> Non-Exec Director		<b>Tony Di Pietro</b> Company Sec / CFO
	<b>Prof Allan Cripps</b> Non-Exec Director		<b>Dr Wayne Jensen</b> R&D Director
			<b>Dr Emily Stein</b> R&D Manager (USA)

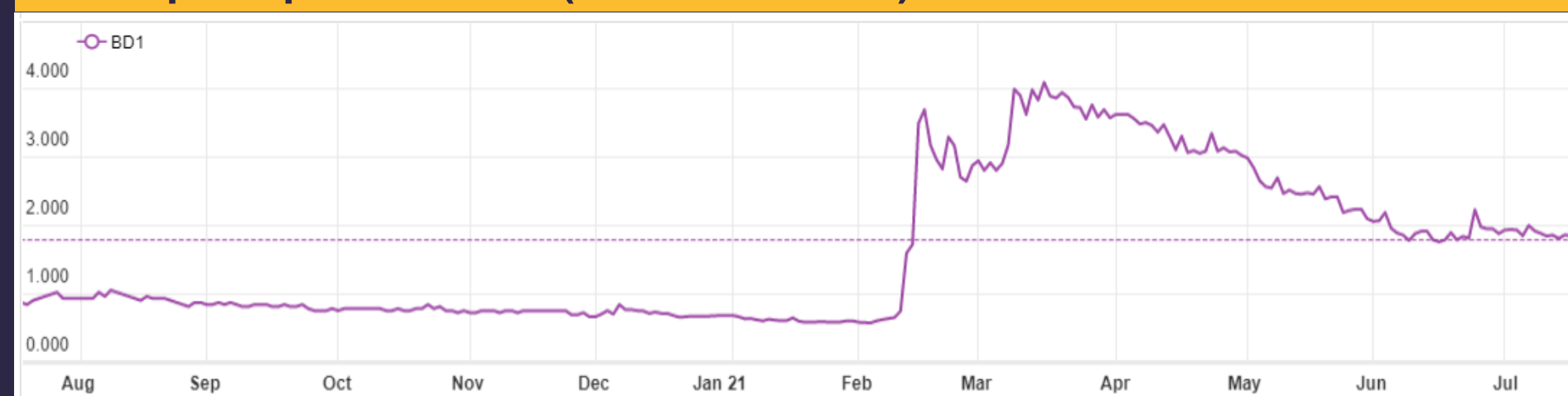
## BARD1 History

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 (20/7/21)

Ordinary shares	80,056,715
Share price	A\$1.80
Market capitalisation	A\$144.1m
Cash position (31/3/21)	A\$6.0m
Quarterly cash burn (31/3/21)	A\$1.5m

## Share price performance (Past 12 months)



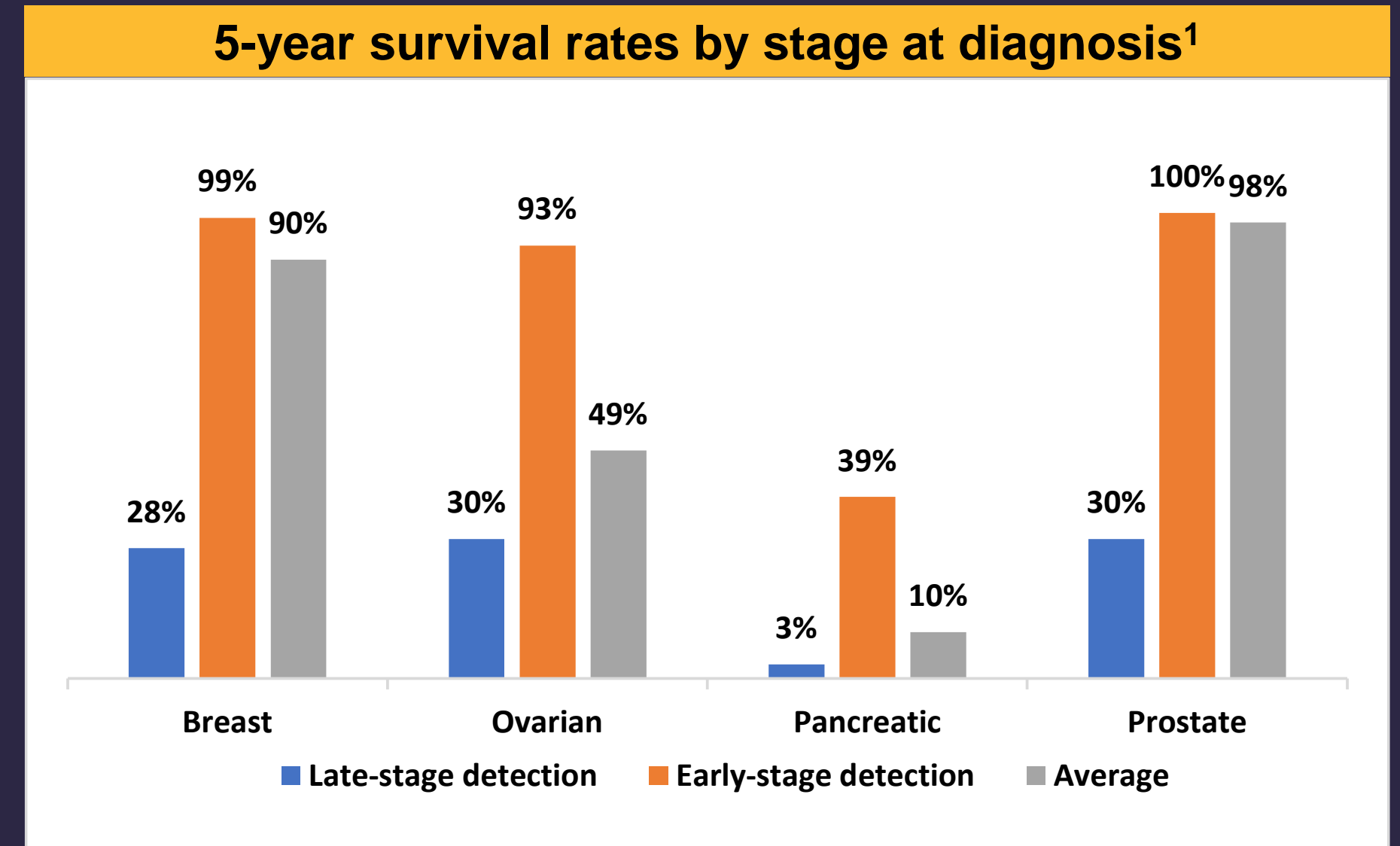
# Unmet need for early cancer detection

## The problem

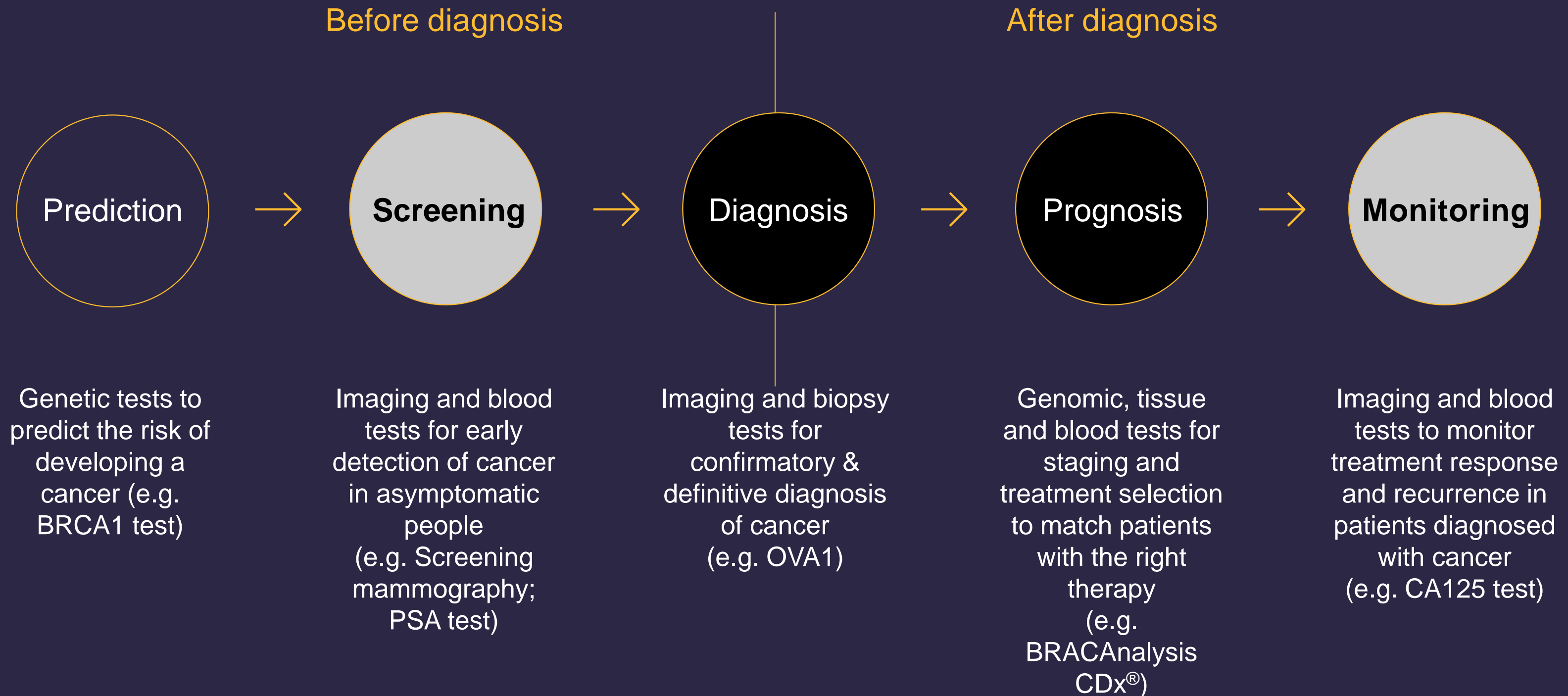
- Screening tests often have high false-positives &/or insufficient sensitivity for early-stage cancer (I/II)
- Cancer often detected at late-stage (III/IV) after symptoms have appeared resulting in poor prognosis
- Poor screening participation due to tests being invasive, inconvenient, ineligible, inaccessible or expensive

## Unmet need

- Unmet need for non-invasive, accurate and reliable screening tests for earlier detection of cancer
- Earlier detection improves treatment options, patient outcomes & 5-year survival<sup>1</sup>
- BARD1 is focused on earlier cancer detection to save lives

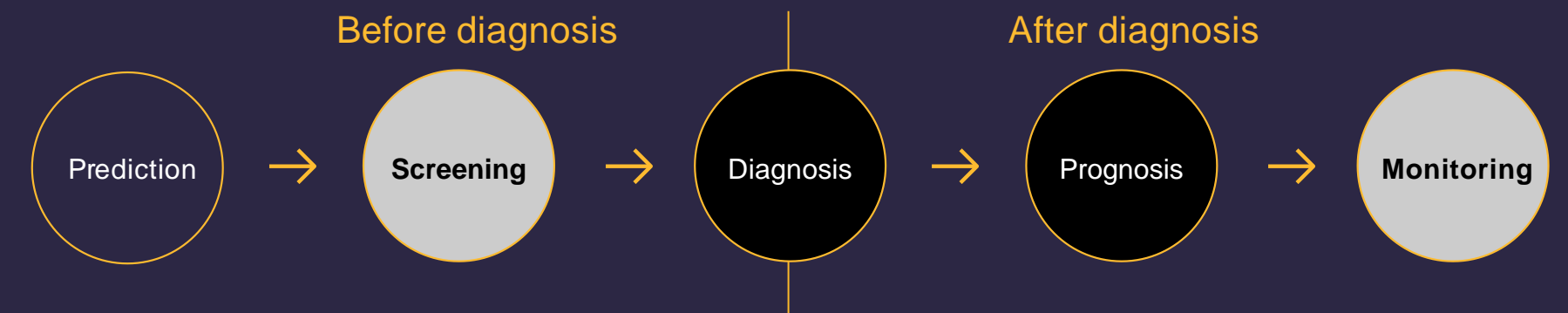


# Diagnostics continuum



# Products and pipeline

- Marketed products for bladder cancer<sup>1</sup> & exosome research
- Lead pipeline products for breast & ovarian cancer
- Focused on cancer screening & monitoring



PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL VALIDATION	MARKETING AUTHORISATION	NEXT MILESTONE
<b>hTERT</b>	Bladder Cancer	ICC (Urine)	Adjunct to cytology	→			In-market	China registration
<b>EXO-NET-RUO</b>	Exosome Capture	Molecular NET (Biofluid)	Research tool	→			In-market	First revenues
<b>SubB2M-BCM</b>	Breast Cancer	ELISA (Serum)	Monitoring	→	<b>LEAD PIPELINE PRODUCTS</b>		2023	Feasibility results
<b>SubB2M-OCM</b>	Ovarian Cancer	ELISA (Serum)	Monitoring	→			2023	Feasibility results
<b>SubB2M-PCS</b>	Prostate Cancer	ELISA (Serum)	Screening	→			**	Feasibility results
<b>SubB2M-PaCS</b>	Pancreatic Cancer	ELISA (Serum)	Screening	→			**	
<b>BARD1-Ovarian</b>	Ovarian Cancer	ELISA (Serum)	Screening	→			**	
<b>BARD1-Breast<sup>2</sup></b>	Breast Cancer	ELISA (Serum)	Screening	→				
<b>BARD1-Lung<sup>2</sup></b>	Lung Cancer	ELISA (Serum)	Screening	→				

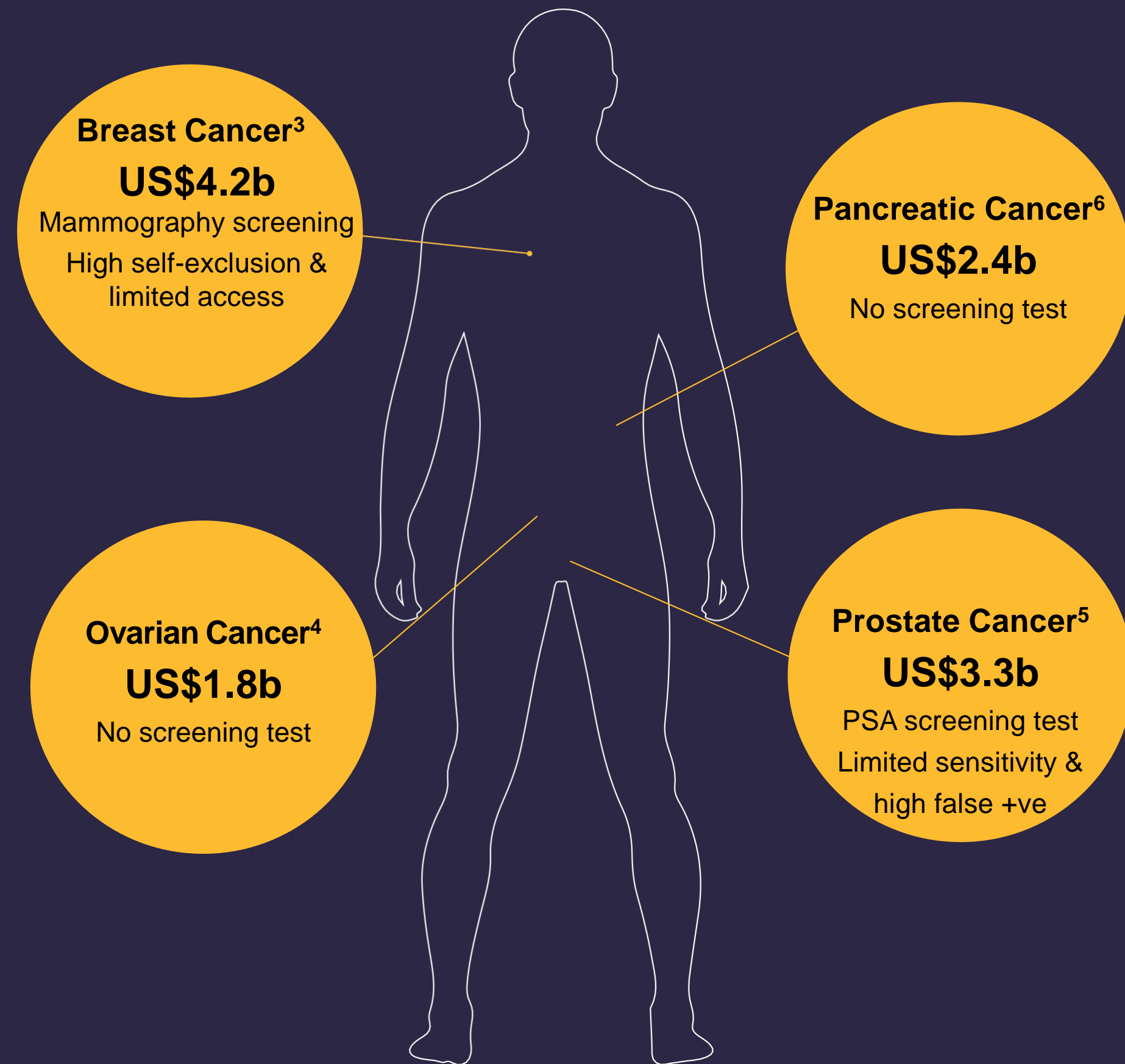
\*RUO = Research Use Only; ELISA = Enzyme Linked Immunosorbent Assay; \*\*Dates will be released when projects are further advanced

<sup>1</sup> Adjunct to urine cytology to assist the detection of bladder cancer; <sup>2</sup> Progression subject to outcome of BARD1-Ovarian results

# Global cancer diagnostics market

- Global cancer burden: 50.6m people<sup>1</sup>
- 19.3m new cases and 10.0m deaths p.a.<sup>1</sup>
- Global cancer diagnostics market worth US\$250b<sup>2</sup>
- BARD1 is targeting markets valued at US\$11b for some of the world's most common and deadliest cancers

#	Cancer <sup>1</sup>	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



<sup>1</sup> GLOBOCAN (IARC) 2020; <sup>2</sup> Grand View Research 2019. <https://www.grandviewresearch.com/press-release/global-cancer-diagnostics-market>; <sup>3</sup> <https://www.grandviewresearch.com/industry-analysis/breast-cancer-diagnostics-market>; <sup>4</sup> <https://www.grandviewresearch.com/industry-analysis/ovarian-cancer-diagnostics-market>; <sup>5</sup> <https://www.grandviewresearch.com/industry-analysis/prostate-cancer-diagnostics-market>; <sup>6</sup> <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>



# SubB2M™ | technology



Game-changing technology for early detection and monitoring of cancer

- **SubB2M** is an engineered protein that specifically binds to a unique sugar Neu5Gc
- **Neu5Gc** is a pan-cancer marker found in human cancer tissues, cells and secretions<sup>1</sup>
- BARD1 has the **exclusive worldwide licence** to SubB2M technology for diagnostic applications<sup>2</sup>
- **Strong patent position** covering composition of matter and method claims for SubB2M and detection of Neu5Gc expressed by tumour cells
- Multiple applications for **early cancer detection and monitoring**
- Focused on developing and commercialising SubB2M-based blood tests for **breast and ovarian cancers**
- ✓ POC results in breast and ovarian cancers show **over 95% sensitivity and 100% specificity** across all cancer stages<sup>3</sup>
- ✓ Small-scale SubB2M supply agreement with University of Adelaide
- ✓ Contract manufacturing agreement for GMP-grade SubB2M being negotiated
- ✓ Collaborative research agreements in place with Institute for Glycomics at Griffith University to develop SubB2M-based blood tests for breast and ovarian cancers
- ✓ Initiated discussions with potential laboratory partners for commercialisation of SubB2M-based blood tests

<sup>1</sup> Neu5Gc is not expressed in normal human tissue; <sup>2</sup> License from University of Adelaide and Griffith University; <sup>3</sup> Shewell et al. *N-glycolylneuraminic acid serum biomarker levels are elevated in breast cancer patients at all stages of disease*. 2021: <https://biorxiv.org/cgi/content/short/2021.06.21.449179v1>

# SubB2M™ | breast cancer test



POC results show >95% sensitivity and 100% specificity for all BC stages

<b>Test</b>	<ul style="list-style-type: none"> <li>• SubB2M-based ELISA for early detection and monitoring of BC</li> </ul>
<b>Results</b>	<ul style="list-style-type: none"> <li>• POC study using SPR-based assay to evaluate detection of Neu5Gc in BC showed &gt;95% sensitivity and 100% specificity across all stages (I - IV) compared to healthy controls<sup>3,4</sup></li> </ul>
<b>Next steps</b>	<ul style="list-style-type: none"> <li>• Feasibility studies to transfer &amp; evaluate ELISA-based test compared to SPR (commenced)<sup>5</sup></li> <li>• Assay development &amp; clinical testing for detection of BC compared to CA15.3</li> <li>• Technical &amp; clinical validation studies by laboratory partner</li> </ul>
<b>Additional research</b>	<ul style="list-style-type: none"> <li>• Expand indications to screening high-risk, asymptomatic women compared to mammography</li> <li>• Expand indications to screening average-risk, asymptomatic women</li> </ul>

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

# Market potential | US breast cancer screening

- World's most common cancer (2.3m new cases & 685k deaths pa)<sup>1</sup>
- US: 3.7m survivors, 234k new cases & 43k deaths pa<sup>1,2</sup>
- Life-time risk of 12.9%<sup>2</sup>
- Screening using mammography recommended for average-risk women<sup>2</sup>
- Issues with high false positives, safety and self-exclusion due to discomfort, inconvenience and cost
- Unmet need for a blood test to screen women who are ineligible, can't access, self-exclude or at high-risk
- Early detection can improve QOL, treatment options & survival (from 29% at late-stage to 99%)<sup>2</sup>

		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<sup>3,4</sup>
- Screening frequency: biennial<sup>4</sup>
- Price: indicative pricing only<sup>5</sup>

# SubB2M™ | ovarian cancer test



POC results show 100% sensitivity and 100% specificity for all OC stages

<b>Test</b>	<ul style="list-style-type: none"> <li>• SubB2M-based ELISA for early detection and monitoring of OC</li> </ul>
<b>Results</b>	<ul style="list-style-type: none"> <li>• POC study using SPR-based assay to evaluate detection of Neu5Gc in OC showed 100% sensitivity and 100% specificity across all stages (I - IV) compared to healthy controls<sup>3,4</sup></li> </ul>
<b>Next steps</b>	<ul style="list-style-type: none"> <li>• Feasibility studies to transfer &amp; evaluate ELISA-based test compared to SPR (commenced)<sup>5</sup></li> <li>• Assay development &amp; clinical testing for detection of OC compared to CA125</li> <li>• Technical &amp; clinical validation studies by laboratory partner</li> </ul>
<b>Additional research</b>	<ul style="list-style-type: none"> <li>• Expand indications to screening high-risk, asymptomatic women</li> <li>• Expand indications to screening average-risk, asymptomatic women</li> </ul>

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

# Market potential | US ovarian cancer screening

- World's deadliest gynaecological cancer (314k new cases & 207k deaths pa)<sup>1</sup>
- US: 235k survivors, 24k new cases & 14k deaths pa<sup>1,2</sup>
- Life-time risk of 1.2%, increases to 35-70% with *BRCA1* mutation<sup>2,4</sup>
- Average 5-year survival 49% due to late-stage detection after symptoms have appeared (57%)<sup>2</sup>
- Screening with CA125 test and TVUS may be offered to high-risk women<sup>4</sup>
- Unmet need for an accurate & reliable screening test for OC
- Early detection can improve QOL, treatment options & survival (from 30% at late-stage to 93%)<sup>2</sup>

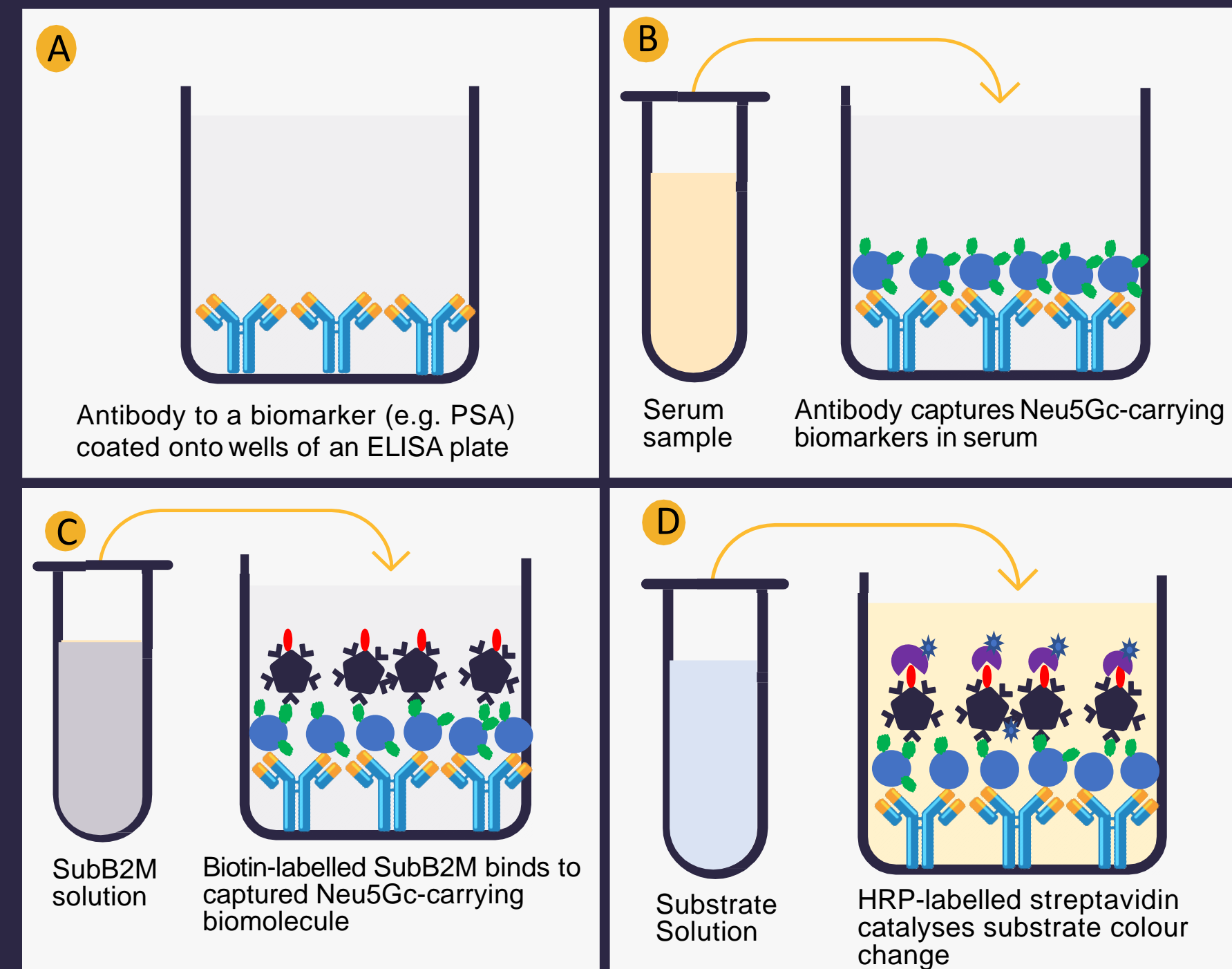
		US Ovarian Cancer Market pa (USD)		
		10%	20%	30%
Indicative Price	Market Penetration			
	\$125	\$0.6 bn	\$1.3 bn	\$1.9 bn
	\$250	\$1.3 bn	\$2.5 bn	\$3.8 bn
	\$500	\$2.5 bn	\$5.1 bn	\$7.6 bn

## Key Assumptions (US market):

- Target population: 50.5m women aged 50 - 74 years<sup>3</sup>
- Screening frequency: annual
- Price: indicative pricing only<sup>5</sup>

# SubB2M™ | ELISA-based test method

- Simple ELISA-based method used in high throughput commercial laboratories worldwide
- Developing **pan-cancer SubB2M test** (ELLBA) for monitoring cancer treatment response or recurrence
- Developing **cancer-specific SubB2M tests** (ELISA) for early detection of cancers based on Neu5Gc carrying tissue-specific biomarkers
- Potential to **improve the specificity of existing commercial cancer tests** and develop fast-to-market, next generation products for detection of ovarian (CA125), breast (CA15.3) and prostate cancers (PSA)

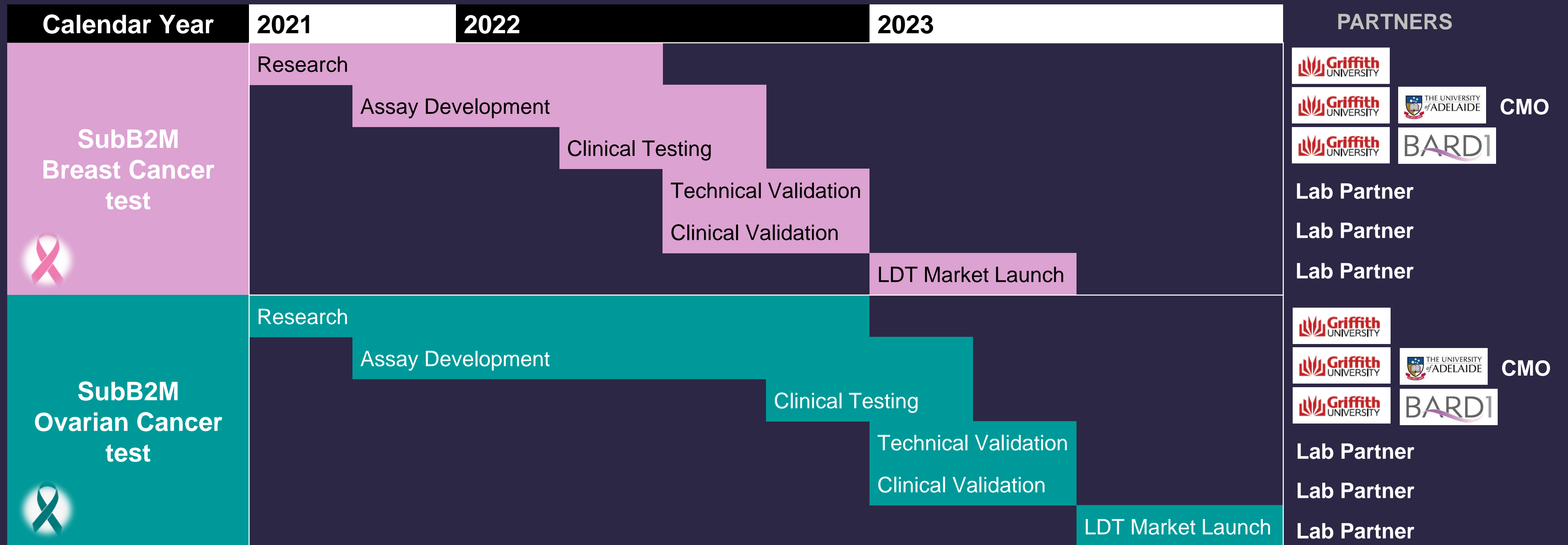


# SubB2M | goals and strategy

GOAL is to develop and commercialise superior blood tests for early cancer detection and monitoring

<b>Develop SubB2M-based ELISA</b>	<ul style="list-style-type: none"><li>• Complete assay development of SubB2M-based ELISA compatible with high-throughput laboratory workflow (assay development)</li></ul>
<b>Advance lead Dx pipeline</b>	<ul style="list-style-type: none"><li>• Advance clinical testing &amp; validation of SubB2M tests for early detection &amp; monitoring of breast and ovarian cancers</li><li>• Analytical validation of reliability (range, LOD, precision, interference, etc)</li><li>• Clinical validation of accuracy (Se, Sp, PPV, NPV &amp; Accuracy)</li></ul>
<b>LDT commercialisation</b>	<ul style="list-style-type: none"><li>• Commercialise first as LDTs with CLIA certified laboratory partner/s in the US</li><li>• Fast-to-market pathway enabling early revenues, access to 'real world' data (acceptable to FDA), build biobank &amp; reimbursement case, and gain market acceptance</li></ul>
<b>IVD regulatory authorisation</b>	<ul style="list-style-type: none"><li>• IVD medical device pathway dependant on use (510k/De Novo/PMA submission)</li><li>• Larger-scale, multi-site clinical studies to prove safety &amp; efficacy in intended use population</li><li>• Enables deeper clinical adoption, market access and reimbursement of kit</li></ul>
<b>Expand applications</b>	<ul style="list-style-type: none"><li>• Expand uses to BC and OC screening in high-risk &amp; average-risk asymptomatic women</li><li>• Expand cancer applications to prostate, pancreatic &amp; others</li><li>• Expand technology applications to improve specificity of CTC, PET &amp; others</li></ul>

# SubB2M | activity timeline





# Other research projects

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



## EXO-NET® technology projects

- EXO-NET is a **molecular NET technology for capture of exosomes**
- **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
- Potential applications as **liquid biopsies** to replace tissue biopsies<sup>1</sup>

Product opportunities:

- **IVD EXO-NET** product for isolation of exosomes for diagnostic purposes
- Exosome-based **cancer diagnostics** using customised IVD EXO-NETs
- Novel exosome-based **companion diagnostics (CDx)**

## BARD1 AAb technology projects

- BARD1 technology **detects autoantibodies to variant BARD1 proteins** associated with cancer formation, progression and poor prognosis
- Potential applications for **early cancer detection**
- **POC studies** performed at UNIGE<sup>2</sup> using a research-stage ELISA show high predictive 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<sup>3</sup>

PRODUCTS <sup>1</sup>	INDICATION	PLATFORM	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL VALIDATION	MARKETING AUTHORISATION*
EXO-NET-001		Molecular NET (Biofluid)		→			
BARD1-Ovarian <sup>3</sup>	Ovarian Cancer	ELISA (Serum)	Screening	→			
BARD1-Breast <sup>4</sup>	Breast Cancer	ELISA (Serum)	Screening	→			
BARD1-Lung <sup>4</sup>	Lung Cancer	ELISA (Serum)	Screening	→			
B009	Type 3c Diabetes	ELISA (Serum)	Screening	→			

# Products



Two products in-market for exosome research and detection of hTERT

## RUO EXO-NET<sup>®</sup> (launched May 2021)



- RUO EXO-NET is a research use only **pan-exosome capture tool**
- Suitable for **blood, urine, saliva** and **cell culture**
- Highly scalable with **speed, purity and yield** advantages
- 1ml vial enables preparation of up to 50 samples
- Available for purchase via [www.exo-net.com](http://www.exo-net.com)
- Multiple evaluations underway with KOLs in academia & industry
- Embeds EXO-NET into the discovery, development & commercialisation phases of future **exosome-based Dx and Tx**
- Research market estimated at **US\$100-500m** by 2026<sup>1</sup>

## 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** as FDA Class I medical device (US), CE Mark (Europe), MFDS Class II (South Korea) & TGA listed (Australia)
- **Distributors appointed** in US, Europe & Asia
- **US:** Generating **revenue, reimbursable & focus on high-volume labs** to drive growth
- **ROW:** 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<sup>2,3</sup>

# Catalysts and plans

Expected value-adding milestones over the next 12 months

## Key catalysts

- **Feasibility results** for SubB2M-ELISA tests (studies commenced)
- **Clinical testing results** for SubB2M-based **breast cancer test**
- **Clinical testing results** for SubB2M-based **ovarian cancer test**
- Secure **laboratory partner/s** for commercialisation of diagnostic pipeline

## Other milestones

- Appoint **distribution partner/s** for RUO EXO-NET®
- Expand co-development / **licensing opportunities** for EXO-NET®

# Capital raising overview

Placement	<ul style="list-style-type: none"><li>▪ The Company has raised A\$15 million via a placement to sophisticated and professional investors (<b>Placement</b>):<ul style="list-style-type: none"><li>▪ Approximately 9.7m new Shares to be issued under the Company's placement capacity under ASX Listing Rules 7.1 &amp; 7.1A</li><li>▪ The Placement <b>was</b> not underwritten</li></ul></li></ul>
Share Purchase Plan	<ul style="list-style-type: none"><li>▪ BARD1 <b>is offering</b> eligible shareholders an opportunity to subscribe for up to A\$30,000 of new Shares under a Share Purchase Plan (<b>SPP</b>) <b>on the same terms as the Placement</b></li><li>▪ It is intended <b>that</b> the SPP will be capped at approximately A\$2 million<sup>1</sup></li><li>▪ Further details will be provided in due course.</li></ul>
Placement <b>and SPP</b> Pricing	<ul style="list-style-type: none"><li>▪ The <b>Placement and SPP</b> offer price of A\$1.55 per share (<b>Offer Price</b>) represents:<ul style="list-style-type: none"><li>▪ A discount of 13.9% to the last close of A\$1.80 on 20 July 2021</li><li>▪ A discount of 14.7% to the 5-day VWAP of A\$1.82 up to and including 20 July 2021</li></ul></li></ul>
Options	<ul style="list-style-type: none"><li>▪ One option will attach to every 2 shares issued under the Placement and SPP. The options will have a 2 year exercise period and the exercise price will <b>be \$2.32</b> (a premium of <b>approximately 50%</b> to the <b>Offer Price</b>)</li></ul>
Lead Manager & Corporate Adviser	<ul style="list-style-type: none"><li>▪ Bell Potter Securities Limited is lead manager to the <b>capital raising</b></li><li>▪ Kidder Williams Ltd is BARD1's corporate adviser</li></ul>

<sup>1</sup>The BD1 Board reserves the right to **scale back, close early and** accept oversubscriptions under the SPP

# Use of Funds

The funds raised under the Offer will be used to expand and advance BARD1's clinical and commercialisation program and strengthen BARD1's balance sheet.

Uses	A\$m
Research & development – predominantly SubB2M tests for ovarian, breast and prostate cancer; and EXO-NET	12.5
Other research, marketing and business development - BARD1 AAb, EXO-NET & hTERT	1.9
Working capital and offer costs	2.6
<b>Total</b>	<b>17.0<sup>2</sup></b>

- Post completion of the **capital raising** BARD1 will have a pro forma cash balance of **approximately \$20.6m<sup>1</sup>**

<sup>1</sup> As at 30 June 2021

<sup>2</sup> Includes \$2m from the SPP

# Indicative Timetable\*

Date	Item
<del>Wednesday, 21 July 2021</del>	<del>Trading halt</del>
Thursday, 22 July 2021	Record date for SPP
Friday, 23 July 2021	Resumption of trading
Thursday, 29 July 2021	Settlement of placement
Friday, 30 July 2021	Lodgement of Prospectus Issue of Placement Shares
Wednesday, 4 August 2021	Dispatch of Prospectus for SPP and Options Offers SPP and Options Offer opens
Wednesday, 18 August 2021	SPP and Options Offer closes
Monday, 23 August 2021	Settlement of SPP
Tuesday, 24 August 2021	Allotment of SPP shares and Options
Wednesday, 25 August 2021	Holding statements despatched and SPP shares and Options commence trading

\* The above timetable is indicative only. The Company, in consultation with the Lead Manager reserves the right to vary the dates and times set out above subject to the Corporations Act and other applicable law.

# 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 Anteo Diagnostics 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 and Arthur Andersen.
- Currently NED Medical Developments International Ltd and 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 PETER FRENCH PhD

Chief Scientific Officer

- Dr Peter French BSc MSc PhD MBA is a biotechnology executive and respected scientist with extensive CSO, CEO and director experience.
- Successful track record in commercialising medical innovations with over 40 years' scientific expertise in cell and molecular biology, and over 40 peer reviewed publications across oncology, oncology, immunology, microbiology and neuroscience.
- Previous leadership roles in academia and industry across diagnostics and therapeutics.



## 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

R&D Manager (USA)

- 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, 27 pending and 2 new provisional patent applications (at 12/7/21)
- Covers key jurisdictions (including US, Europe, Asia & Australia)

Patent Family	Title	Granted	Pending	Expiry
<b>SubB2M</b>				
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
<b>BARD1</b>				
PCT/FR01/02731 (WO/2002/018536)	Truncated BARD1 protein, and its diagnostic and therapeutic uses	JP, US		JP 2021 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, US(cont)	BR, SG	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	US (cont)	2035
<b>hTERT</b>				
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	AU, CN, EP, IL, US	2036
<b>Molecular NETs</b>				
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

# Key risks

This section includes details of the key risks attaching to an investment in BARD1 securities. These risks may affect the future operating and financial performance of BARD1 and the value of BARD1 securities. Before deciding whether to invest in BARD1 securities, you should consider whether such an investment is suitable for you having regard to publicly available information (including this Presentation), your personal circumstances and following consultation with a financial or other professional adviser. Additional risks and uncertainties that BARD1 is unaware of, or that it currently considers to be immaterial, may also become important factors that adversely affect BARD1's operating and financial performance.

You should note that the occurrence or consequences of many of the risks described in this Section are partially or completely outside the control of BARD1, its directors and senior management. Further, you should note that this section focuses on the potential key risks and does not purport to list every risk that BARD1 may have now or in the future. It is also important to note that there can be no guarantee that BARD1 will achieve its stated objectives or that any forward looking statements or forecasts contained in this Presentation will be realised or otherwise eventuate. All potential investors should satisfy themselves that they have a sufficient understanding of these matters, including the risks described in this Section, and have regard to their own investment objectives, financial circumstances and taxation position.

The risks described in this Section are categorised as follows:

- (1) specific risks of an investment in BARD1; and
- (2) general risks and risks associated with the Offer.

SPECIFIC RISK	DESCRIPTION
<b>SPP</b>	The SPP component of the Offer is not underwritten, which may result in a shortfall in the proceeds expected under the SPP. Should such a shortfall occur, BARD1 may need to limit the use of the funds raised under the Offer accordingly.
<b>Dilution</b>	Current holders of BARD1 securities who do not participate in the Offer as per their entitlement will have their shareholding in BARD1 diluted. Investors may also have their investment diluted by future capital raisings or issues of new equity securities by BARD1. BARD1 may issue new equity securities in the future to fund further development and/or commercialisation of cancer diagnostic tests which may, under certain circumstances, dilute the value of a BARD1 securityholder's interest in BARD1.
<b>Product development risk</b>	<p>There are many risks inherent in the development of diagnostic products, including that projects can be delayed or fail to meet outcomes or demonstrate any benefit, or research may cease to be viable for a range of scientific, regulatory and commercial reasons.</p> <p>BARD1's diagnostic pipeline products will require substantial further research, development and validation, and future clinical studies (which carry the risk of technology transfer failure, clinical validation failure and other adverse outcomes for BARD1).</p> <p>Regulatory review or approval may be required to conduct clinical studies in some jurisdictions, and there is no assurance that any regulatory or review body will allow BARD1 to undertake such studies or that approvals to conduct such studies will be granted in a timely manner. Any delays in securing relevant approvals from regulatory or review bodies may result in substantial delays and/or increases in costs.</p> <p>If BARD1's diagnostic products are not ultimately proven to be effective for diagnostic or monitoring purposes, BARD1's business and resulting value may be materially harmed. Until the development and validation studies are completed, there is no certainty that the products will reach development milestones or be effective for diagnostic or monitoring purposes.</p>

# Key risks (cont.)

SPECIFIC RISK	DESCRIPTION
<b>Commercialisation risk</b>	<p>It is likely that BARD1 will need to form marketing and/or product development alliances with third parties for BARD1 products in countries which BARD1 seeks to commercialise (subject to ongoing legal and regulatory compliance and financial viability to market or develop such products). BARD1 will rely on its ability and that of its partners to develop and commercialise its products in order to create future revenue. Any products developed by BARD1 will require extensive clinical testing, regulatory approval and significant marketing efforts before they can be sold and generate revenue. BARD1's efforts to generate revenue may not succeed for a number of reasons including issues or delays in the development, testing, regulatory approval, marketing or reimbursement of these products or services. There is no assurance that suitable partnerships will be secured or commercialise BARD1 products, which may have adverse impacts on BARD1's operating results and financial position.</p> <p>Additionally, should BARD1 elect to commercialise its products directly in any countries, it would be required to invest significant time and resources to build direct sales, distribution and marketing capabilities, and it would be required to ensure compliance with all legal and regulatory requirements for sales, marketing and distribution. Furthermore, even if BARD1 does not achieve commercialisation of any of its products and services, it may not be able to sustain its efforts or otherwise achieve commercialisation to a degree which would support the ongoing viability of its operations.</p> <p>A failure to successfully develop and commercialise BARD1's products could lead to a loss of opportunities and adversely impact on BARD1's operating results and financial position. In those countries where BARD1 seeks to commercialise its products through distributors or other third parties, BARD1 will rely heavily on the ability of its partners to effectively market and sell its products and services.</p>
<b>Intellectual property protection</b>	<p>The value of BARD1 is strongly linked to its intellectual property. As of 12 July 2021, the Company has 34 granted patents and 27 pending patent applications across BARD1, hTERT, Molecular NETs, and SubB2M technology platforms. Maintaining this value is therefore dependent on BARD1's ability to protect its intellectual property. There is no guarantee that BARD1's patent rights comprise all of the rights that BARD1 needs to be entitled to freely use and commercialise its products. If third party patents or patent applications contain claims infringed by BARD1's technology and these claims are valid, BARD1 may be unable to obtain licences to these patents at a reasonable cost, if at all, and may also be unable to develop or obtain alternative technology. If such licences cannot be obtained at a reasonable cost, the business could be significantly impacted. Furthermore, the enforceability of the patents owned by BARD1 may be challenged and BARD1's patents could be partially or wholly invalidated following challenged by third parties. Each jurisdiction has its own patent laws and particular requirements that need to be met for the grant of a patent. There may be changes to patent law or its interpretation by the courts in a particular jurisdiction from time to time, which may have an impact on patents in the relevant country.</p> <p>A decision of the High Court of Australia (D'Arcy v Myriad Genetics 2015 HCA 35) has held that claims to isolated nucleic acids (in particular a nucleic acid coding for a BRCA1 protein with one or more specified variations indicative of susceptibility to breast or ovarian cancer) are not patentable subject matter, and it is unclear whether the decision will only impact nucleic acids (which are considered to essentially relate to genetic information), or will also apply to isolated nucleic acids that are functional in nature (for example, inhibitory RNA, ribozymes, etc.). A more recent decision of the Australian Patent Office considers that inhibitory RNA is not simply genetic information and is therefore patentable subject matter. The United States is an important jurisdiction. Recent decisions of the United States Supreme Court have increased the threshold for what constitutes patentable subject matter in the United States. In these decisions, broadly drafted claims to diagnostic methods were held to be directed to unpatentable subject matter. These decisions led to the United States Patent and Trademarks Office (USPTO) issuing specific guidance to patent examiners for examining claims directed to diagnostic methods. The guidelines indicate that where a claim is directed to monitoring an increase or a decrease in the level of a marker as a diagnostic indication, without any further or additional features, that such a claim is unlikely to be directed to patentable subject matter. Examples of "something more" that transform a claim from an unpatentable "law of nature" to a patentable diagnostic method include the use of unconventional technologies. We note the United States courts are under no obligation to follow such guidance by the USPTO and the patentability of diagnostic method claims and the ultimate scope and validity of granted claims in this area will be uncertain for some time. There is no guarantee that BARD1 will be able to maintain and successfully exploit the patents within its patent portfolio. BARD1 also relies on protecting trade secrets, and the protective measures employed may not always be sufficient. Any failure in the measures implemented to protect intellectual property may result in an erosion of any potential competitive position.</p> <p>There is no guarantee that any further patent applications will be granted or that the Company's owned and licensed patent rights comprise all the rights that the Company should have acquired to be entitled to freely use and commercialise its products.</p>
<b>Litigation</b>	<p>As previously announced, Tony Walker and Dr Irmgard Irminger-Finger (former Founding Scientist of BARD1), being the original founders and major shareholders of BARD1's wholly owned subsidiary BARD1AG SA, have commenced legal proceedings against BARD1 in the Supreme Court of Victoria. BARD1 has been served with a Writ and Statement of Claim.</p> <p>The proceedings relate to Performance Shares in BARD1 issued to the plaintiffs as part consideration under the agreements under which BARD1 acquired BARD1AG SA. Following the 30 for 1 share consolidation approved by BARD1 shareholders, Dr Irmgard Irminger-Finger holds a total of 3,608,414 performance shares and Tony Walker holds a total of 2,950,055 performance shares. Conversion of each of the Performance Shares into one ordinary share in BARD1 was subject to the achievement of certain milestones related to BARD1's Lung Cancer Test before the expiry date, being 9 June 2021. The Statement of Claim alleges among other things that BARD1 was subject to obligations to do all things as were reasonably necessary to seek to have the Test satisfy the milestones by the expiry date and not to deprive the plaintiffs of the opportunity to have each of their Performance Shares convert into one ordinary share in BARD1. The Statement of Claim further alleges that in breach of those obligations the plaintiffs have been deprived of that opportunity. The proceedings seek damages, costs, interest and such further or other orders as the Court considers just.</p> <p>BARD1 has filed a defence denying the above claims and allegations with the Court and the matter is now proceeding through the Court process. BARD1 has recently been served with particulars of the plaintiffs' alleged loss and damage. BARD1 has recently announced to ASX relevant details of these particulars. BARD1 may also in the future be subject to litigation, claims and disputes in the course of its business, including competitor disputes, consumer disputes, supplier disputes, employment dispute, contractual disputes, disputes with governmental agencies or authorities or regulators, indemnity claims, and occupational and personal claims.</p> <p>Any such matters (including the present legal proceedings) could involve prosecution, defence, and settlement costs, and consume management time in the dealing with any such litigation, claims and disputes.</p>

# Key risks (cont.)

SPECIFIC RISK	DESCRIPTION
<b>Reliance on key personnel</b>	BARD1 currently employs, or engages as consultants, a number of key management and scientific personnel and seeks to engage further personnel. The failure to recruit new personnel, or the loss of any existing personnel could materially and adversely affect BARD1 and may impede the achievement of its research, product development and commercialisation objectives. There can be no assurance that BARD1 will be able to attract, retain and motivate appropriately qualified and experienced additional staff and this may adversely affect BARD1's prospects for success.
<b>Competition</b>	BARD1 operates in the life sciences and diagnostic industries that are highly competitive, and include companies that have substantially greater financial, technical, research and development, and marketing resources than BARD1. There are companies that compete with BARD1's efforts to develop, validate and commercialise diagnostic products and other product candidates. BARD1's competitors may discover, develop, validate and commercialise products in advance of BARD1, and/or products that are more effective, more economical or materially superior to those developed by BARD1. Consequently, BARD1's current or future technologies and products may become obsolete or uncompetitive, resulting in adverse effects on BARD1's revenues, margins and ultimately its profitability.
<b>Government and regulatory factors</b>	<p>The diagnostic industry is regulated in Australia, the United States, Europe and other countries in which BARD1 may conduct business operations or seek to commercialise its products. BARD1 has not yet formally engaged with the TGA (Australia), FDA (USA), Notified Bodies (Europe) and other regulatory authorities to establish the optimal regulatory pathway/s and clinical study plans for its diagnostic products in key jurisdictions. While BARD1 is not aware of any reason why its cancer diagnostic products would not be able to advance to clinical validation stage, BARD1 cannot guarantee that this will occur in a timely manner or at all. Additionally, BARD1 may fail to gain marketing or regulatory approval in Australia, the US, EU, or other jurisdictions for its cancer diagnostics products.</p> <p>BARD1 will be subject to the laws and regulations of Australia and each country in which it operates. Any amendment to existing legislation or regulations in countries where BARD1 operates and plans to operate may adversely affect BARD1's business operations. Any actual or alleged breach of such legislation or regulation could result in BARD1 being subject to remedial actions, such as product recalls, or penalties, or litigation, which may be more stringent than those in Australia. Additionally, following commercialisation of any BARD1 products (which may not occur), BARD1 will be subject to the laws and regulations concerning the post market surveillance of medical device products in the market.</p> <p>Changes in government legislation and policy in those jurisdictions in which BARD1 operates or plans to operate, in particular changes in taxation, royalties, compliance with environmental regulations, export, workplace health and safety, chain of responsibility, intellectual property, customs, tariffs, franchising and competition laws, may affect the future earnings, asset values and the relative attractiveness of investing in BARD1. Furthermore, BARD1 operates in foreign jurisdictions where business may be affected by changes implemented by foreign governments.</p>
<b>Manufacturing / Production Risks</b>	Production of a diagnostic antibody for the hTERT product is a low risk undertaking for an experienced and capable manufacturer. Nonetheless, there is some risk that batches manufactured for sale do not pass acceptance testing or are rejected for quality control reasons, leading to an inability to supply product to the market.
<b>Healthcare Insurers and Reimbursement</b>	In both domestic and foreign markets, sales of products are likely to depend in part upon the availability and amounts of reimbursement from third party healthcare payer organisations, including government agencies, private healthcare insurers, self-insured employee plans and other healthcare payers such as health maintenance organisations. In most major markets, there is considerable pressure to reduce the cost of healthcare. No assurance can be given that reimbursement will continue to be provided by such payors at all, or without substantial delay, or that reimbursement amounts will be sufficient to enable the Company to sell products developed on a profitable basis.

# Key risks (cont.)

SPECIFIC RISK	DESCRIPTION
<b>Price of BARD1 Shares</b>	<p>There are general risks associated with investments in equity capital such as BARD1 securities. The trading price of BARD1 securities may fluctuate with movements in equity capital markets in Australia and internationally. There is no assurance that the price of BARD1 securities will increase in the future, even if BARD1 achieves key technical or commercial milestones or any future financial forecasts. The price at which BARD1 securities are quoted on the ASX may increase or decrease due to a number of factors, some of which may not relate directly or indirectly to BARD1's performance or prospects.</p> <p>Generally applicable factors which may affect the market price of BARD1 securities include:</p> <ul style="list-style-type: none"> <li>- fluctuations in the domestic and international markets for listed securities;</li> <li>- general economic conditions, including interest rates, inflation rates, exchange rates, commodity and oil prices or changes to government;</li> <li>- fiscal, monetary or regulatory policies, legislation or regulation;</li> <li>- inclusion in or removal from market indices;</li> <li>- the nature of the markets in which BARD1 operates;</li> <li>- variations in sector performance, which can lead to investors exiting one sector to prefer another; and</li> <li>- initiatives by other sector participants which may lead to investors switching from one company's securities to another.</li> </ul> <p>Deterioration of general economic conditions may also affect BARD1's business operations, and the consequent returns from any prospective or potential investment in BARD1. In the future, the sale of large parcels of BARD1 securities may cause a decline in the price at which BARD1 securities trade on ASX.</p> <p>BARD1 securities carry no guarantee in respect of profitability, dividends, return on capital, or the price at which they may trade on the ASX. There are a number of national and international market factors that may affect the price of BARD1 securities, including movements on international stock markets, economic conditions and general economic outlook, interest rates, exchange rates, inflation rates, commodity supply and demand, government taxation and royalties, legislation, monetary and other policy changes and general investors' perceptions. Neither BARD1 nor the BARD1 Directors have control over these factors.</p>
<b>Infringement of third party intellectual property</b>	<p>If a third party accuses BARD1 of infringing its intellectual property rights or if a third party commences litigation against BARD1 for the infringement of patent or other intellectual property rights, BARD1 may incur significant costs in defending such action, whether or not it ultimately prevails. Typically, patent litigation in the pharmaceutical and biotechnology industry is expensive. Costs that BARD1 incurs in defending third party infringement actions would also include diversion of management's and technical personnel's time. In addition, parties making claims against BARD1 may be able to obtain injunctive or other equitable relief that could prevent BARD1 from further developing or commercialising its products. In the event of a successful claim of infringement against BARD1, it may be required to pay damages and obtain one or more licences from the prevailing third party. If it is not able to obtain these licences at a reasonable cost, if at all, it could encounter delays in product development and commercialisation, and loss of substantial resources while it attempts to develop alternative products. Defence of any lawsuit or failure to obtain any of these licences could prevent BARD1 or its partners from commercialising products and could cause it to incur substantial expenditure.</p>
<b>Special reputational risks</b>	<p>Any BARD1 products that are successfully commercialised will be marketed in an industry where a product failure could have serious consequences. Any product failure, product recall or product liability claim is likely to disrupt BARD1's business operations and may cause reputational harm by leading medical professionals and other consumers to doubt product accuracy, safety or quality, adversely impacting BARD1's financial performance. Additionally, any negative news or controversies about the diagnostics industry, cancer diagnostic products or BARD1 may impact BARD1's reputation and or the market acceptance of its products.</p>
<b>Product liability</b>	<p>The testing, marketing and future sale of BARD1's products whether directly or through future licensees involves a risk of product liability claims or litigation being brought against BARD1, including if any products fail to effectively diagnose cancer in accordance with its product claims. If this occurs, BARD1 may have to expend significant financial resources to defend any proceedings. Furthermore, if the action against BARD1 is successful, this may result in the removal of regulatory approval for the relevant products and/or monetary damages being awarded against BARD1. BARD1 will seek to limit its liability for such claims in its agreements with future licensees and customers and may also be entitled to be indemnified by its licensees in various circumstances. However, limitations of liability are not necessarily effective at law and indemnification may not always be available. BARD1 intends to maintain product liability insurance in respect of its products. However, if BARD1 is unable to obtain sufficient product liability insurance at an acceptable cost then BARD1's liability could exceed BARD1's insurance coverage.</p>

# Key risks (cont.)

SPECIFIC RISK	DESCRIPTION
<b>Ukrainian gold projects matters</b>	As has been previously announced by BARD1, on 10 July 2007, BARD1's group disposed of its Ukrainian gold mining assets for US\$5,000,000. US\$3,000,000 of this amount remains outstanding and will only be received after the purchaser meets a regulatory milestone relating to the advancement of the Saulyak Gold Project; being the grant of a mining licence. BARD1 has been advised by its Ukrainian advisers that the mining licence has been granted, but this has not been acknowledged by the purchaser. BARD1 will keep the market informed of any relevant information it receives but stresses that it is yet to confirm whether BARD1 has a present right to be paid the US\$3 million and makes no statement of whether such a right will exist, or whether in any event BARD1 would receive those funds. No investment decision should be made on the basis of these matters. In addition, as BARD1 has previously announced, it has guaranteed the payment of a royalty by Saulyak Limited Liability Company based on gold output from the Saulyak Gold Project which was disposed of by BARD1 on 10 July 2007 (as described above). The royalty is up to 2% net smelter royalty per ounce of gold produced from the Saulyak Gold Project payable only in respect of ounces of gold produced over 750,000 ounces in total. Gold production from the Saulyak Gold Project has not commenced. At the time of the sale of the project by BARD1, total reserves identified at the project were not in excess of 750,000 ounces.
<b>Foreign exchange risks</b>	BARD1's financial reports are prepared in AUD. However, BARD1 earns revenues denominated in USD and incurs expenditure denominated in CHF and USD. BARD1 does not currently hedge against movements in foreign exchange rates. Any adverse movements in currencies against the AUD could adversely impact BARD1's financial performance and position.
<b>ASX listing</b>	ASX imposes various listing obligations on BARD1 which must be complied with on an ongoing basis. While BARD1 must comply with its listing obligations, there can be no assurance that the requirements necessary to maintain the listing of BARD1's securities on the securities exchange operated by ASX, will continue to be met or will remain unchanged.
<b>Historic Eurogold Limited litigation</b>	Eurogold Limited, a former name of BARD1, is named in an appeal application before the High Commercial Court of the Republic of Serbia. The appeal, by the Republic of Serbia, is currently stayed (but not struck out) and relates to a claim by the then State Union of Serbia and Montenegro which was dismissed by the Commercial Court in Belgrade on 4 October 2005. The origins of the claim were a contamination incident which occurred in Romania in January 2000 that allegedly involved Arul S.A., a Romanian joint stock corporation in which BARD1 (then named Esmeralda Limited) held shares. BARD1's Board considers that in light of the period of time which has elapsed since the original claim was filed, the favourable decision in the court at first instance and the similarities between Australian law and Serbian law with respect to the liability of shareholders for the acts or omissions of the company in which those shares are held, the risk of any liability, actual or contingent, of BARD1 arising from the appeal application generally, or in Serbia in particular arising from the 2000 contamination incident are remote.



# Key risks (cont.)

GENERAL RISK	DESCRIPTION
<b>Liquidity</b>	<p>BARD1 securities are only listed on the securities exchange operated by ASX and will not be listed for trading on any other financial markets, other than Chi-X. There can be no guarantee that an active market in BARD1 securities will continue. If an active market for BARD1 securities is not sustained, it may be difficult for holders of BARD1 securities to sell their securities at the time or for the price they seek. Furthermore, the market price for BARD1 securities may fall or be made more volatile because of relatively low volume of trading in BARD1 securities.</p> <p>When trading volume is low, significant price movements can be caused by the trading in a relatively small number of shares. Sales of a substantial number of BARD1 securities or the perception or expectation that such sales may occur, could cause the market price of BARD1 securities to decline. BARD1 may also offer securities in order to raise capital or to (part) fund future acquisitions, which may adversely affect the market price for the securities.</p>
<b>Dilution</b>	<p>BARD1 may issue equity securities in the future to fund further research, development and/or commercialisation of cancer diagnostic tests which may, under certain circumstances, dilute the value of an interest in BARD1.</p>
<b>Access to capital</b>	<p>BARD1 may need to rely on access to debt and equity financing. The ability to secure financing on acceptable terms may be materially adversely affected by volatility in financial markets, either globally or impacting a particular geographic region, industry or economic sector, or by a downgrade in BARD1's credit rating. For these (or other) reasons, financing may be unavailable or the cost of financing may be significantly increased. Such inability to obtain, or such increase to the costs of obtaining financing could materially adversely affect BARD1's operations or financial performance.</p>
<b>Tax law and application</b>	<p>The application of and change in, relevant tax laws (including income tax, goods and services tax (or equivalent), rules relating to deductible liabilities and stamp duty), or changes in the way those tax laws are interpreted, will or may impact the tax liabilities of BARD1 or the tax treatment of an investment in BARD1. An interpretation or application of tax laws or regulations by a relevant tax authority that is contrary to BARD1's view of those laws may increase the amount of tax paid or payable by BARD1.</p> <p>Both the level and basis of tax may change. Any changes to the current rate of company income tax (in Australia or other countries in which BARD1 operates now or in the future) and / or any changes in tax rules and tax arrangements (again in Australia or other countries in which BARD1 operates now or in the future) may increase the amount of tax paid or payable by BARD1, may impact a holder of BARD1 securities' returns and could also have an adverse impact on the level of dividend franking / conduit foreign income and a holder of BARD1 securities' returns. In addition, an investment in BARD1 securities involves tax considerations which may differ for each holder of BARD1 securities. Each holder of BARD1 securities is encouraged to seek professional tax advice in connection with any potential or prospective investment in BARD1.</p> <p>BARD1 has received research and development (R&amp;D) tax incentives for expenditure that has been incurred in the past. Under the R&amp;D incentive framework, both the Australian Taxation Office and AusIndustry are entitled to audit the expenditure incurred on R&amp;D activities to ensure that it has been incurred in accordance with requirements of Division 355 of the Income Tax Assessment Act 1997 (Division 355). To this extent, there is a risk that the some or all of the R&amp;D tax incentives received to date could be required to be repaid (together with interest and penalties) if audits of the claims are conducted and the relevant regulatory authority forms the view that the requirements of Division 355 have not been met in full or in part. Additionally, there is no guarantee of the continuation of the R&amp;D incentive program. If the program ceases or if there is a material adverse change made, BARD1 may lose a significant sources of funds which may inhibit the Company's product development and commercialisation objectives.</p> <p>The Company has received cash flows, and anticipates the future receipts, from refundable tax credits of the federal government's R &amp; D tax incentive scheme. There is no guarantee that the Australian Federal Government will not change its R&amp;D tax incentive program. If the program ceases or a material adverse change is made to the refundable component of the program, a significant funding gap would result, jeopardising the achievement of the Company's product development and commercialisation objectives.</p>
<b>Unforeseen expenses</b>	<p>BARD1 may be subject to significant unforeseen expenses or actions. This may include unplanned operating expenses, future legal actions or expenses in relation to future unforeseen events.</p>
<b>Ability to service or refinance debt</b>	<p>BARD1 may become unable to service or refinance any future debt, or obtain new debt, on acceptable terms or at all, depending on future performance and cash flows of BARD1 which are affected by various factors, some of which may be outside BARD1's control, such as interest and exchange rates, general economic conditions and global financial markets. If any of these scenarios materialise in an adverse way, BARD1 may be unable to raise financing on acceptable terms to repay maturing indebtedness. This could adversely affect the longer term prospects and financial performance of BARD1's business.</p>
<b>Accounting standards</b>	<p>Australian Accounting Standards (AAS) are adopted by the Australian Accounting Standards Board (AASB) and are not within the control of BARD1 or its directors. The AASB may, from time to time, introduce new or refined AAS, which may affect the future measurement and recognition of key statement of profit or loss and statement of financial position items. There is also a risk that interpretation of existing AAS, including those relating to the measurement and recognition of key statement of profit or loss or statement of financial position items may differ. Any changes to the AAS or to the interpretation of those standards may have an adverse effect on the reported financial performance and position of BARD1.</p>

# Key risks (cont.)

GENERAL RISK	DESCRIPTION
<b>COVID-19</b>	<p>The current global COVID-19 pandemic may continue to impact existing product revenues for hTERT and may impact the BARD1's early-stage research projects or development programs. Many clinical laboratories have shifted focus to COVID-19 testing rather than elective Dx tests. However, at this stage, BARD1's directors do not believe that COVID-19 is likely to have any material impact on BARD1's development pipeline, although it could cause delays or interruption to future prospective clinical studies if another similar outbreak coincided with a future study.</p> <p>The global impact of the COVID-19 pandemic, and the advice and responses from health and regulatory authorities, is continuously developing. The global economic outlook is facing uncertainty due to the COVID-19 pandemic which has had and may continue to have a significant impact on capital markets and share prices. BARD1's directors are closely monitoring the situation and considering the impact on the Company's business from both a financial and operational perspective. To date, COVID-19 has affected equity markets, governmental action, regulatory policy, quarantining, self-isolations and travel restrictions. These impacts are creating risks for BARD1's business and operations in the short to medium term.</p>
<b>Insurance risks</b>	<p>Although BARD1 maintains insurance, no assurance can be given that adequate insurance will continue to be available to BARD1 in the future on commercially acceptable terms.</p>
<b>Force majeure events</b>	<p>Events may occur within or outside Australia that could impact on global, Australian or other local economies relevant to BARD1's financial performance, the operations of BARD1 and the price of BARD1 securities. These events include but are not limited to acts of terrorism, an outbreak of international hostilities, fires, floods, earthquakes, labour strikes, civil wars, natural disasters, outbreaks of disease or other man-made or natural events or occurrences that can have an adverse effect on the demand for BARD1's services and its ability to conduct business. BARD1 has only a limited ability to insure against some of these risks.</p>
<b>Climate risk</b>	<p>Natural events caused or affected by changing climate can have an impact on BARD1's business. Conditions may influence the supply of and demand for diagnostics products and services provided by BARD1, resulting in varied revenue levels. Climate change may have financial implications for BARD1 and could potentially cause direct damage to assets and indirect impacts caused by supply chain or product distribution disruption. It is also possible that climate change may result in an increased cancer risk which would result in greater demand for diagnostic products. However, at this stage, it is not possible to quantify that potential increased demand (if any).</p>