



BARD1

LIFE SCIENCES LIMITED

Early cancer detection to save lives

COMPANY PRESENTATION

19 November 2018

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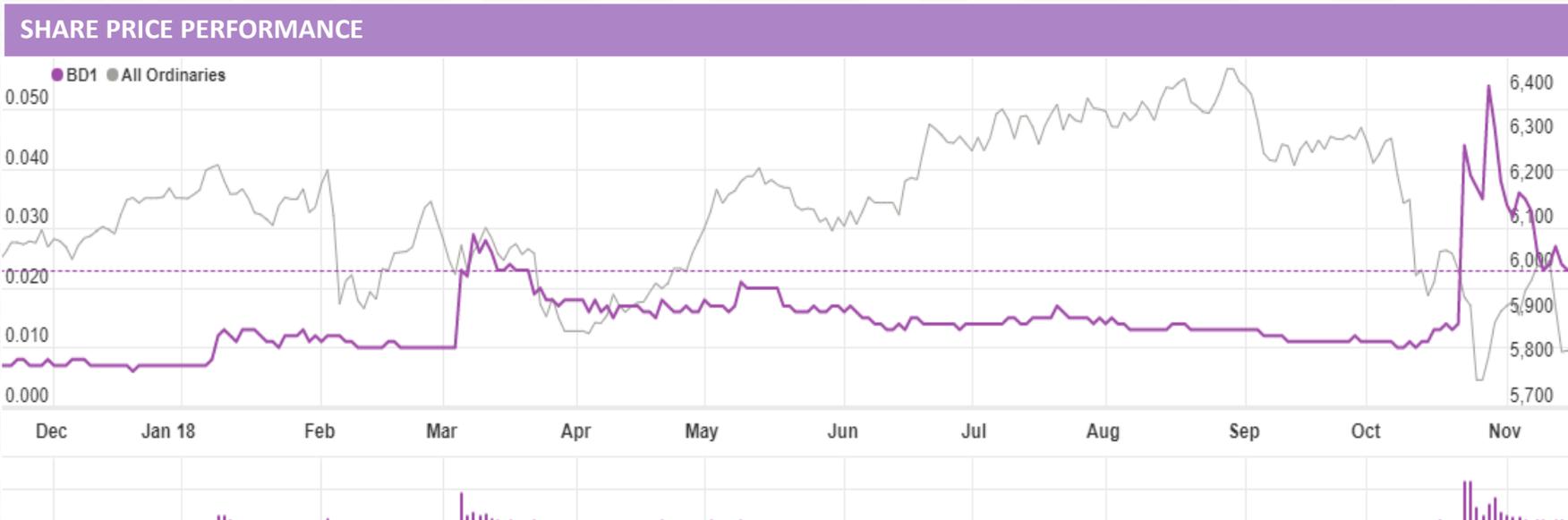
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BARD1 Life Sciences

Medtech company focused on developing and commercialising non-invasive diagnostics for early detection of cancer to save lives

FINANCIAL INFORMATION		TOP SHAREHOLDERS (16/11/18)		
Ticker	ASX:BD1	Irmgard Irminger-Finger	# SHARES	% HOLDING
Share Price (@16/11/18)	A\$0.023	Peter Gunzburg	108,252,420	13.06%
Ordinary Shares	828.66m	Tony Walker	29,835,004	3.60%
Market Capitalisation (@16/11/18)	A\$19.06m	Universite de Geneve	26,501,626	3.20%
52w H/L Range	A\$0.075-0.006	Top 20 Holders	266,489,434	32.16%
Cash (@30/9/18)	A\$1.13m	TOTAL	828,662,398	100.00%
Average Daily Volume (3mo)	47.53m			

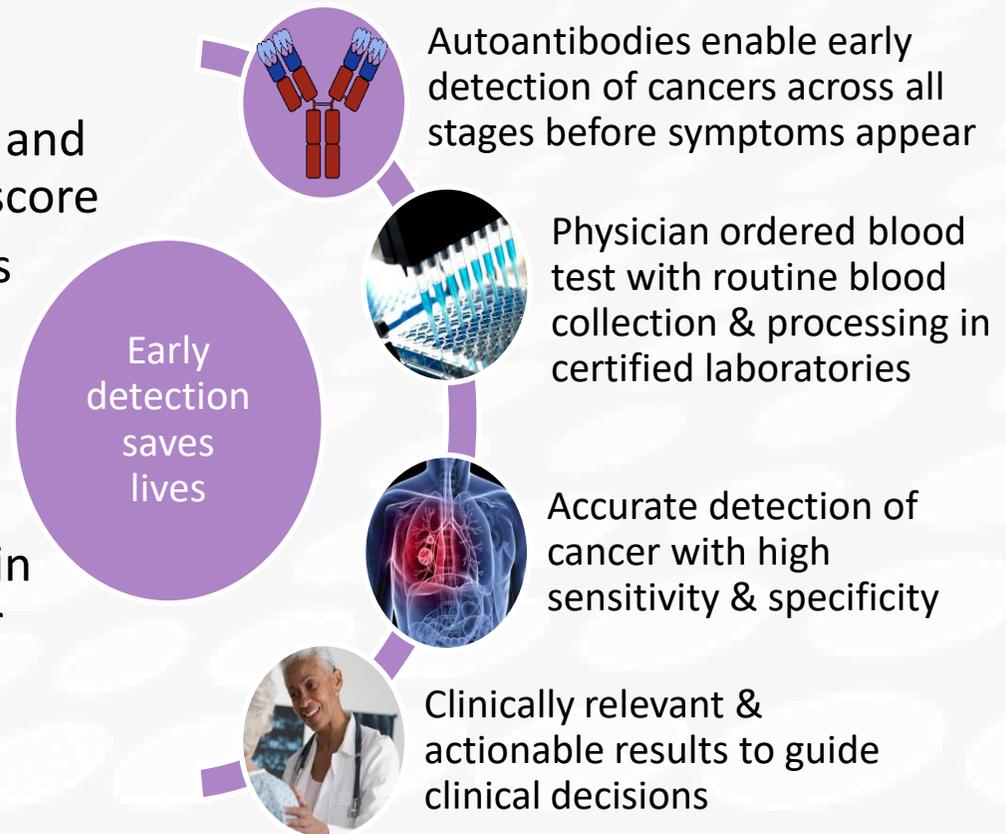


Investment Highlights

- **Medtech company** focused on developing non-invasive diagnostics for early detection of cancer to save lives
- **Proprietary tumour marker platform** with strong IP protecting biomarkers, methods and use
- **Targeting unmet needs** in burgeoning US\$101B global cancer diagnostics market
- **Case-control studies** showing accuracy of BARD1 autoantibody panels for detection of breast, ovarian and lung cancers with high sensitivity & specificity
- **Assay development** underway to transfer, develop & validate BARD1 tests on Luminex[®] instrumentation
- **Focus** on commercializing BARD1-Ovarian and new BARD1-Breast cancer tests to take advantage of synergies in women with HBOC*
- **Clinical studies** expected to commence in 2H19 and market launch by 1H21
- **Pipeline** includes BARD1-Lung the world's deadliest cancer
- Exploring multiple **partnering and corporate opportunities** to deliver shareholder value
- Value-adding milestones and **news flow expected in next 6-12 months**

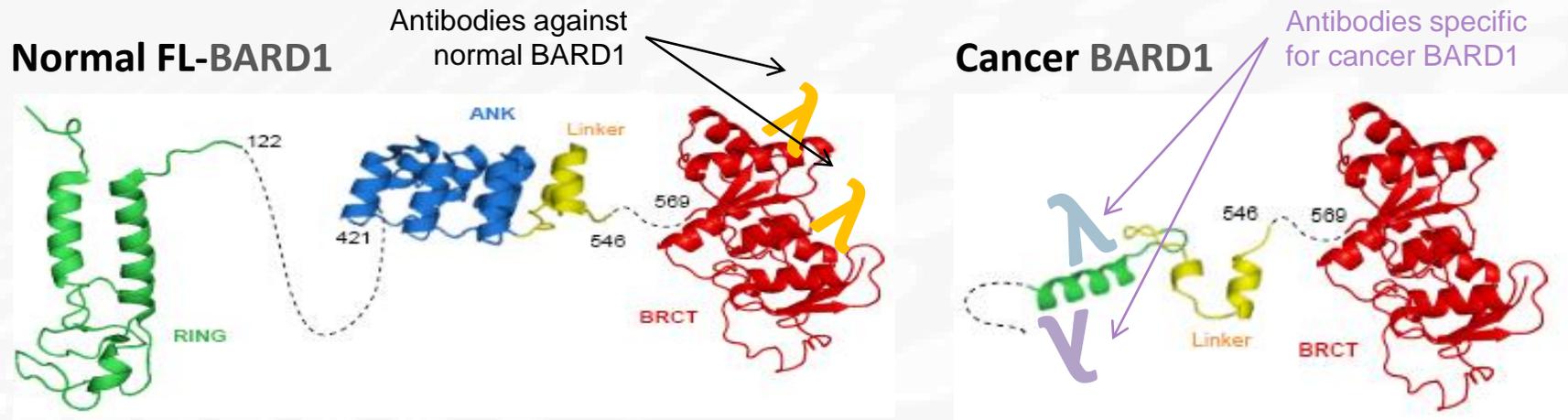
Behind BARD1's diagnostic success

- Proprietary tumour marker platform and diagnostic approach
- BARD1 blood tests measure autoantibodies to BARD1 proteins and use an algorithm to give a cancer score
- Autoantibodies indicate the body's early immune response to cancer, present in early stages before symptoms appear
- Existing blood tests often detect tumour-associated antigens, high in late stages after symptoms appear
- Targeting unmet need for early detection of cancer
- Early detection enables earlier treatment, improves patient outcomes, save lives and reduces healthcare costs



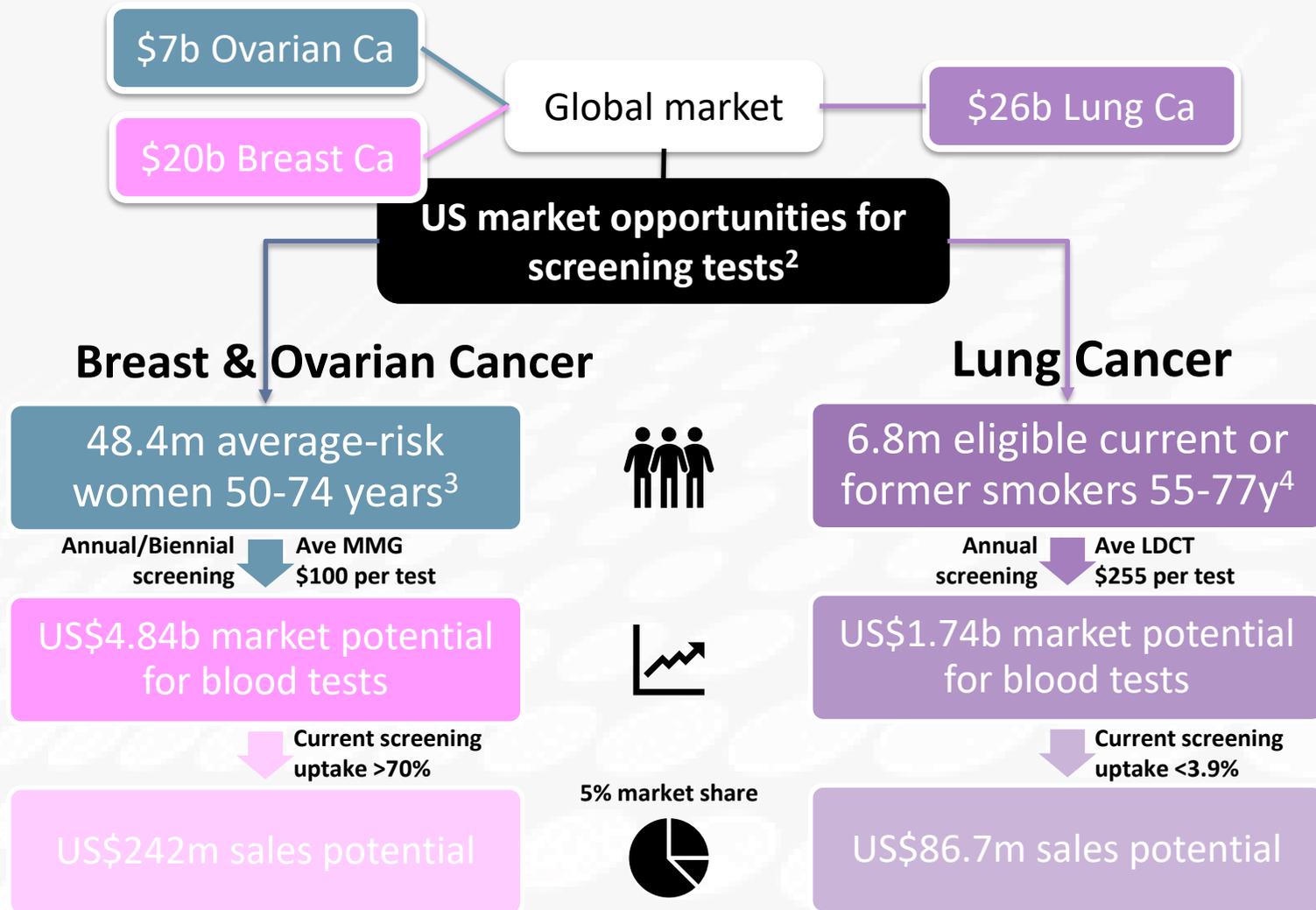
Proprietary BARD1 tumour marker platform

- Normal cells express **BARD1 protein (FL)** that functions as a *tumour suppressor* to prevent cancer
- Cancer cells express variant **BARD1 isoforms** that drive *tumour formation* and are correlated with cancer progression and poor prognosis
- BARD1 isoforms are immunogenic and induce **BARD1 autoantibodies** reflecting the early *immune response to cancer*



- **BARD1 platform** has potential applications across multiple cancers including ovarian, breast, lung, colorectal and prostate cancers
- **Strong IP** protecting biomarkers, methods and use

Focused on unmet needs in Global Cancer Diagnostics Market of US\$101b¹



1. Transparency Market Research 2014; 2. Company estimates; 3. Statista 2017; 4. ACS 2017

Breast Cancer is the biggest cancer killer of women

■ Breast Cancer is the **most common cancer in women** worldwide

- World: 2.1m new cases & 627k deaths pa
- US: 266k new cases & 41k deaths pa

■ **Risk factors** include age >55 years (69%), family history (<15%), and BRCA1/2 mutations (5-10%)

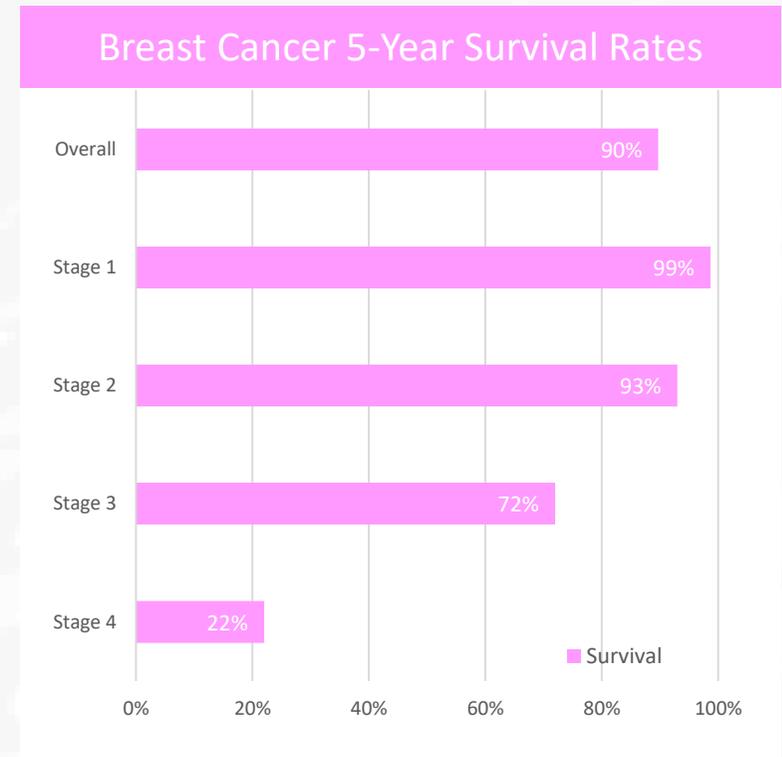
■ **Life-time risk**



■ **Good overall 5-year survival** of 90% due to screening, awareness and treatments

■ **Screening recommended** with mammograms in *average-risk asymptomatic women* aged 45+ years, annual MRI/mammogram in *high-risk* women aged 30+

■ **No blood test approved for early detection**



Source: <https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html>

BARD1-Breast a world-first solution

Blood test in development for **early detection of breast cancer**

- **Measures** BARD1 autoantibodies in the blood to give a breast cancer score
- Breakthrough case-control study in 174 samples shows **86% accurate for early detection of breast cancer** in women across common subtypes and all stages with **70% sensitivity & 88% specificity**
- **Accurately distinguishes malignant and benign lesions** with 85% sensitivity & 76% specificity enabling risk assessment of malignancy following a suspicious mammogram

Study	n (cancer:normal)	Model AUC	Test AUC	Sensitivity	Specificity
BC-001a (model)	123 (61:64)	0.94	0.86	70%	88%
BC-001b (benign)	110 (61:49)		0.84	85%	76%

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.

- **Same autoantibody test method and Luminex® instrumentation** as BARD1-Ovarian enabling fast development & parallel clinical testing
- Clinical studies expected to commence 2019 to evaluate clinical performance as a **screening test for early detection of breast cancer in average-risk asymptomatic women**
- Potential to **detect breast cancer early, increase screening uptake, improve survival and reduce healthcare costs**

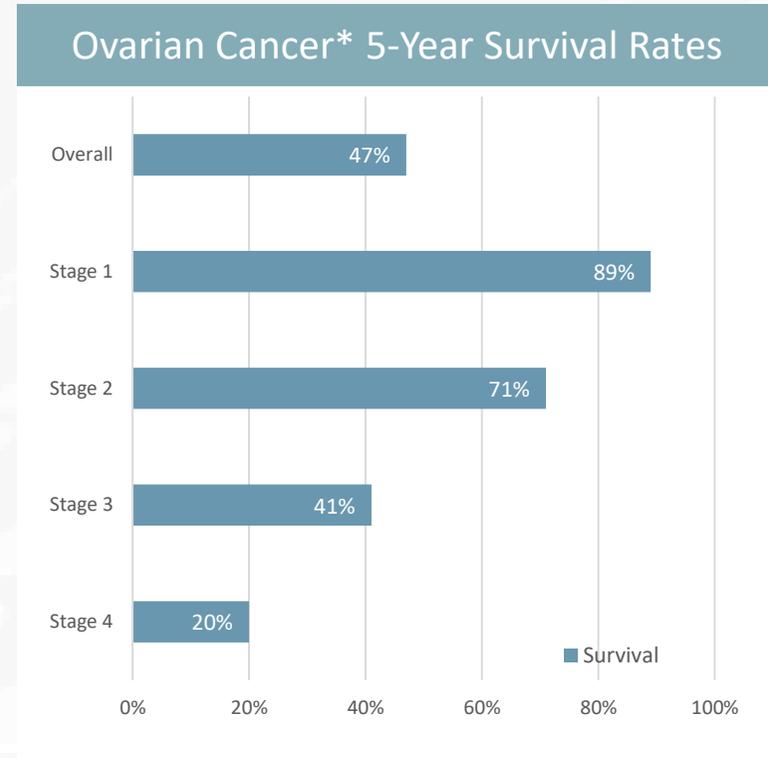
Ovarian Cancer continues to devastate

- Ovarian Cancer is the **leading cause of gynecological cancer deaths**
 - World: 295k new cases & 185k deaths pa
 - US: 22k new cases & 14k deaths pa
- **Risk factors** include age >55 years (70%), family history (<10%), and BRCA1/2 mutations (5-10%)

- **Life-time risk**



- **Low overall 5-year survival** of 47% since 65% diagnosed at late-stage since no screening program
- **Early-detection saves lives** increasing survival to 89%
- **Screening not recommended** with TVUS or CA125 in *average-risk asymptomatic women*, whereas screening with TVUS and CA125 may be offered in *high-risk* women
- **No blood test approved for early detection**



*All Epithelial subtypes (90% of all cases)

Source: <https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21456>

BARD1-Ovarian changes the landscape

Blood test in development for early detection of ovarian cancer

- **Measures** BARD1 autoantibodies and CA125 in the blood to give an ovarian cancer score
- **7 case-control studies** in 743 samples show excellent diagnostic accuracy of AUC 0.95 for early detection of ovarian cancer across all stages
- **Industry leading results in average-risk women** with addition of CA125 biomarker achieving 88% sensitivity & 93% specificity
- **97% accurate in high-risk women** with family history of breast/ovarian cancer or carrying *BRCA1/2* mutations achieving 89% sensitivity & 97% specificity

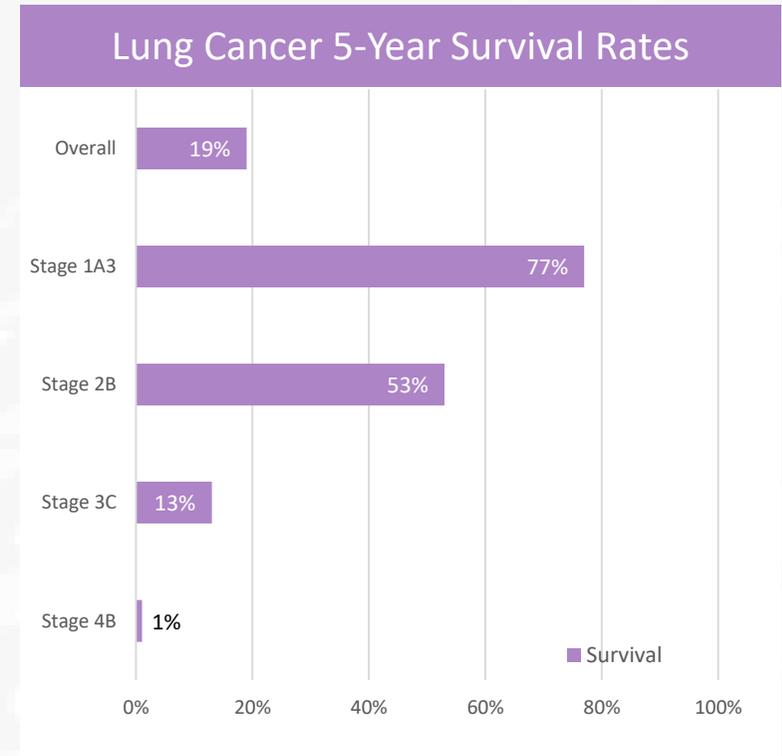
Study	n (cancer:normal)	Model AUC	Test AUC	Sensitivity	Specificity
OC-CA125	400 (200:200)	0.98	0.95	88%	93%
OC-R001	261 (127:134)	0.99	0.97	89%	97%

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.

- Assay development by Thermo Fisher underway to transfer test to **Luminex® instrumentation**
- Clinical studies expected to commence 2019 to evaluate clinical performance as a **monitoring test for early detection of ovarian cancer in high-risk women with HBOC**
- Potential to detect ovarian cancer early, save women's lives and avoid unnecessary surgery

Lung Cancer remains the biggest cancer killer

- Lung Cancer is the **leading cause of cancer deaths** worldwide
 - World: 2.1m new cases & 1.8m deaths pa
 - US: 234k new cases & 154k deaths pa
- **Risk factors** include age >55 years (91%) and smoking (>80%)
- **Poor overall 5-year survival** of 18.6% since over 57% diagnosed at late-stage
- **Early-detection saves lives** increasing survival to over 77%
- **Screening recommended** with annual CT scan in *high-risk asymptomatic adults aged 55-80 years with >30 pack-year smoking history* (USPSTF 2014)
- **No blood test** approved for early detection



Source: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/detection-diagnosis-staging/survival-rates.html>

BARD1-Lung test

Blood test in development for **early detection of lung cancer**

- **Measures** BARD1 autoantibodies in the blood to give a lung cancer score
- **2 case-control studies** in 628 samples shows high accuracy for early detection of lung cancer with up to **80% sensitivity and 77% specificity**, and promising results for gender-specific algorithms with model AUC=0.91 in males and AUC-0.89 in females

Study	n (cancer:normal)	Model AUC	Test AUC	Sensitivity	Specificity
LC-POC	187 (94:93)	0.96	0.86	80%	77%
LC-600	628 (395:233)	0.85	0.80	80%	68%

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.

- **Publication** of POC results and diagnostic method in peer-reviewed journal *PloS ONE*
- **Assay development** planned for 2H19 to optimise and validate test on Luminex[®] instrumentation using additional biomarkers & gender-specific algorithms
- Clinical studies required to evaluate clinical performance as a **screening test for early detection of lung cancer in high-risk asymptomatic individuals**
- Potential to **detect lung cancer early, save lives and reduce healthcare costs**

BARD1-Vaccine

Exploratory research program for a **potential cancer vaccine**

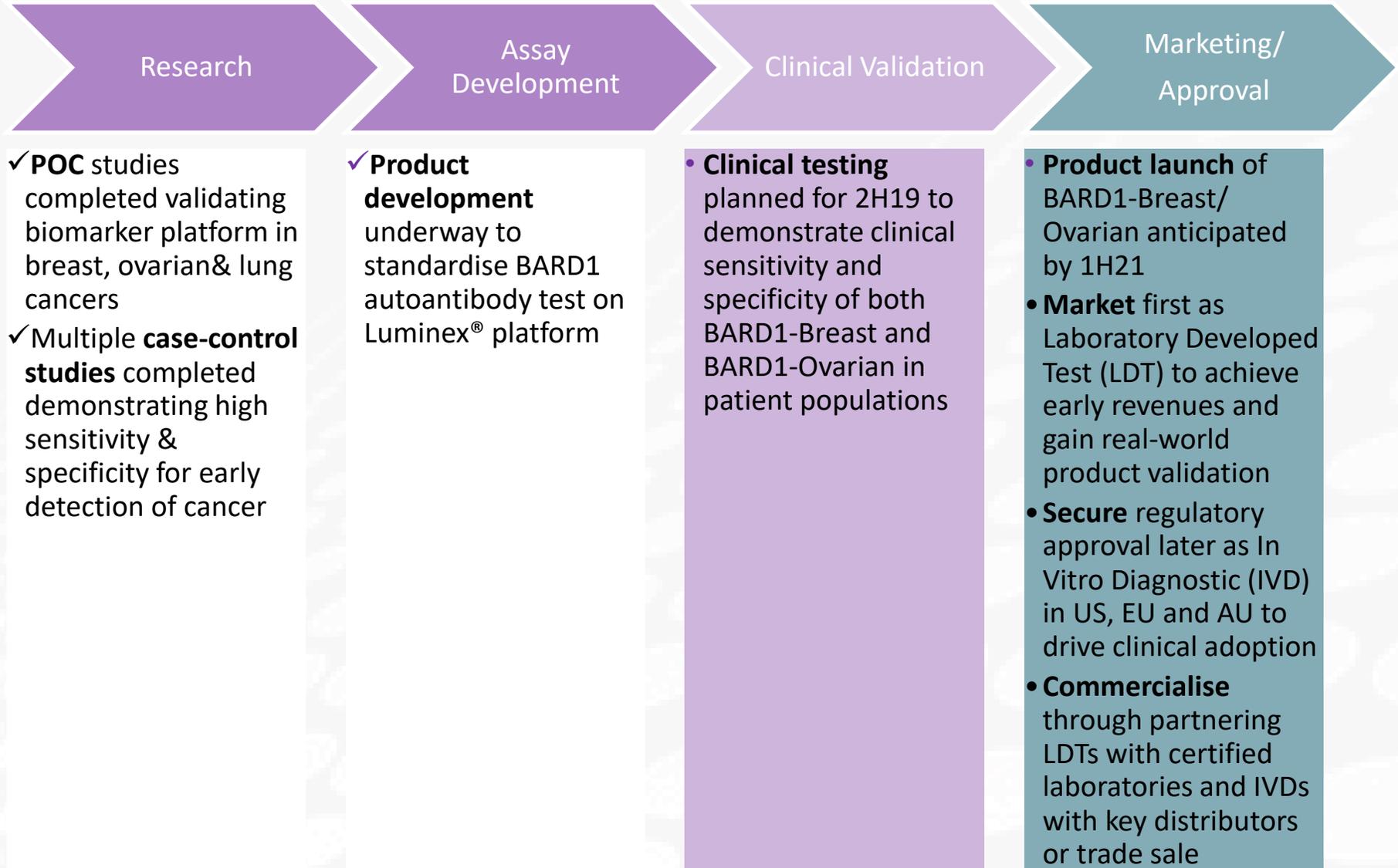
- **OBJECTIVE:** POC study to evaluate BARD1 peptide vaccine formulations for cancer prevention and/or treatment in murine cancer models to assess in vivo effectiveness for reducing tumour size, inhibiting tumour growth and/or inducing an effective immune response
- **PRELIMINARY RESULTS:**
 - Malignant mesothelioma: Encouraging initial results showing delayed tumour growth
 - Lung and colon cancers: Analysis incomplete
- **ONGOING ANALYSIS:**
 - Breast cancer
 - Tumour inflammatory cell profile
- **FINAL RESULTS:** Expected in Dec-18
- **FUTURE RESEARCH:**
 - Determine methods to improve immune response
 - Determine effectiveness of BARD1-Vaccine in combination with therapies

BARD1 Key Milestones

CY	2018		2019				2020	2021
	Q3	Q4	Q1	Q2	Q3	Q4		
BARD1 <i>Ovarian</i>	Assay Dev				Clinical Validation		Launch	
BARD1 <i>Breast</i>		Assay Dev			Clinical Validation		Launch	
BARD1 <i>Lung</i>					Assay Dev			
Research	R&D to advance other Dx for early cancer detection							
	IRH cancer vaccine research							
Commercial	BD and partnerships							
		New patents & publications						

Timelines subject to change according to clinical and regulatory advice

Commercialisation Strategy



BARD1's Intellectual Property Portfolio

- 5 patent families covering various BARD1 DNA & protein sequences, methods of diagnosis & treatment, and use in multiple cancers

Patent Family 5	Title	Granted 10	Pending 19	Expiry
PCT/FR01/02731	Truncated BARD1 protein and its diagnostic and therapeutic uses	US, JP		2021
PCT/IB2011/053635	BARD1 isoforms in lung and colorectal cancer and use thereof	US, JP, JP (div), IL, CN, CN div, AU	US (divisional), EP, CA, BR, SG, HK	2031*
PCT/IB2011/054194	Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof	US	EP	2031*
PCT/EP2014/073834	Lung Cancer Diagnosis		US, EP, CA, JP, IL, CN, AU, SG, KR, HK	2034*
EP14002398.7	Novel non-coding RNA, cancer target and compounds for cancer treatment		US	2035*

*Plus any extension of term in the US due to prosecution delay

Significant Achievements 2018

Date	Announcements
9/1/18	✓ OC-400 results showing 82% sensitivity and 79% specificity for detection of ovarian cancer
2/2/18	✓ JP Divisional Patent granted providing broader protection for lung & colorectal cancer
6/3/18	✓ OC-400V results showing 89% sensitivity and 82% specificity in independent test set
21/3/18	✓ IL Patent granted covering BARD1-Lung
22/3/18	✓ Capital Raising of \$1.3m to institutional and professional investors
18/5/18	✓ Contract Development Agreement signed with TF to transfer research assay to Luminex® instrumentation
19/6/18	✓ OC-125 results with addition of CA125 showing 88% sensitivity and 93% specificity in average-risk women
12/7/18	✓ US Patent granted covering BARD1-Ovarian & BARD1-Breast
6/9/18	✓ OC-R001 results showing 89% sensitivity and 97% specificity in high-risk women
23/10/18	✓ NEW BC-001 results showing high accuracy of BARD1-Breast for detection of breast cancer with 70% sensitivity and 88% specificity
24/10/18	✓ Chinese Divisional Patent granted covering BARD1-Lung

Expected news flow in next 12 months

BARD1-Ovarian

- Complete Assay Development and technical validation on Luminex® instrumentation – 1Q19
- Commence clinical studies for BARD1-Breast and BARD1-Ovarian for early detection of breast and ovarian cancers – 2H19

Pipeline

- ✓ Results from research studies for other cancers (breast) – 4Q18
- Results from BARD1-Vaccine mouse studies – 4Q18
- Initiate further product development for BARD1-Lung – 2H19

Commercial

- Additional patents and publications – 1H19
- Progress corporate and partnering discussions – 1H19
- Strengthen Board and management – 1H19

Peer Valuations | BD1 has significant growth potential



NASDAQ:VRML US\$37.7m
 FDA-cleared IVDs OVA1® & Overa® for risk assessment of ovarian cancer with up to 92% sens & 69% spec.



AIM:ONC £59.5

Marketed LDT 2009 & CE-IVD 2017 *EarlyCDT*®-Lung with 41% sens & 93% spec. Jan-18 license with Genostics for China 8-12.5% royalties + £10m equity investment @49% premium. May-18 launch *EarlyCDT*-Liver.



ASX:BD1 A\$19.06m

Development-stage blood tests for early detection of breast, ovarian and lung cancers.



XETRA:ECX €76.0

FDA-approved & CE-IVD mark Epi proColon® for detection of colorectal cancer in US, EU & China. Jul-17 failed takeover offer by Summit Hero Holding for shares @49.2% premium to 3mo VWAP.



ASX:RHY A\$15.1m

Development-stage ColoSTAT™ blood test for early detection of colorectal cancer.



ASX:SDX A\$22.5m

Marketed Class 1 IVD for detection of hTERT in urothelial cells (bladder cancer) in US, EU & AU.

Leadership Team



PETER GUNZBURG BCom | Chairman

Public company director, stockbroker & technology investor, with 20+ years corporate advisory, capital raising, transaction & business management experience. Currently Chair of the Institute for Respiratory Health at UWA. Previously Director of Resolute Ltd, Australian Stock Exchange Ltd, Eyres Reed Ltd, CIBC World Markets Australia Ltd and Fleetwood Corporation Ltd.



DR IRMGARD IRMINGER-FINGER PhD | Executive Director & Chief Scientific Officer

Founder and co-inventor of BARD1 and its technology, European Woman Entrepreneur Award finalist 2014, and internationally recognised expert in tumour biology with over 100 publications, several patents, and multiple international collaborations and keynote conference presentations. Currently Adjunct Prof at UWA. Former Privat Docent at UNIGE, Executive Director and founder of BARD1AG SA.



BRETT MONTGOMERY | Non-Executive Director

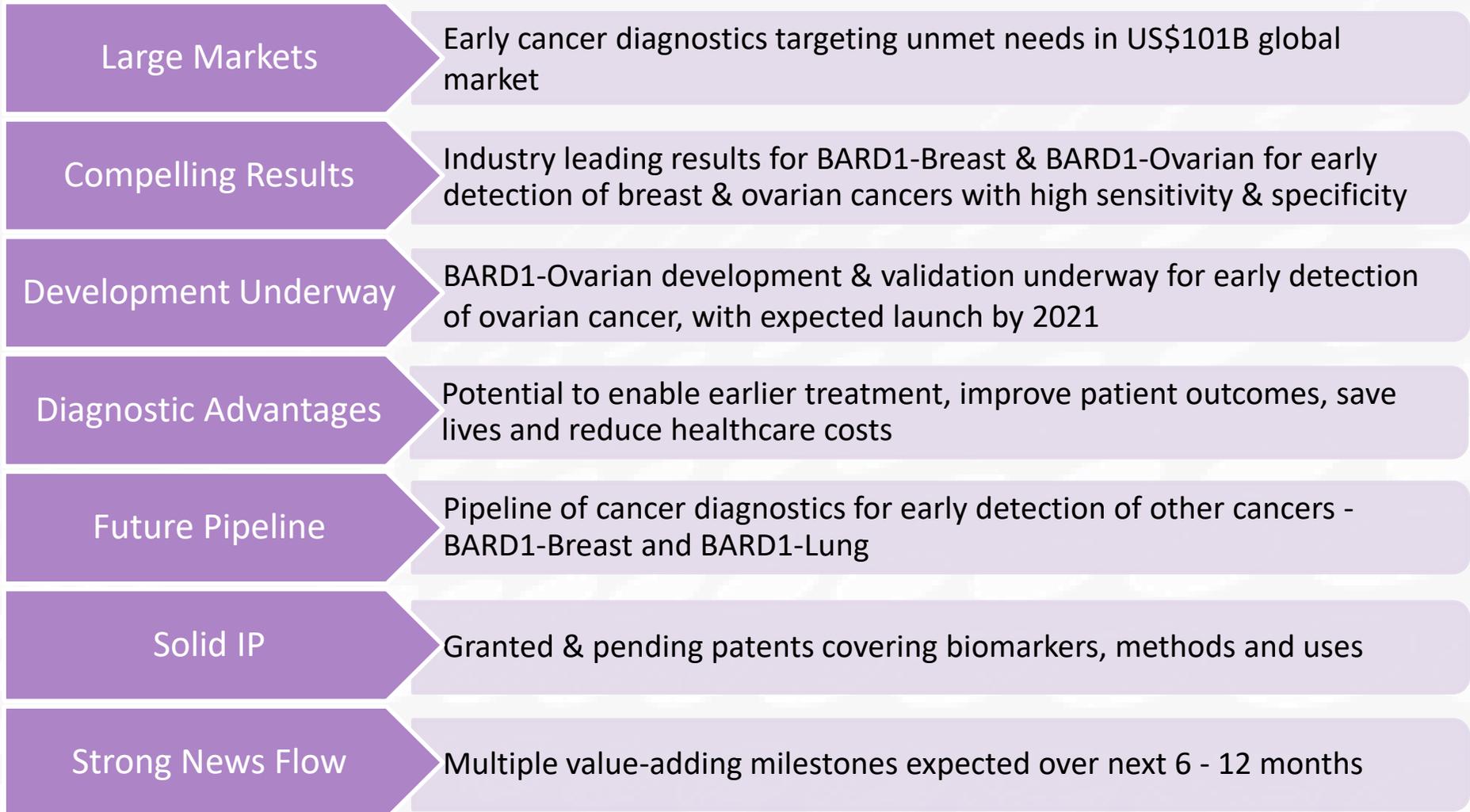
Public company director with extensive experience in leadership, mining company management, corporate governance and risk management. Currently Non-Executive Director of Tanami Gold NL. Previously Managing Director Kalimantan Gold NL, and Director of Magnum Gas and Power Ltd, Grants Patch Mining Ltd and EZA Corporation Ltd.



DR LEEARNE HINCH BVMS MBA | Chief Executive Officer

Accomplished public company CEO and biotechnology consultant with extensive leadership, strategy, fundraising, operational, business development and commercial experience across drugs, devices, diagnostics and animal health. Currently MD of commercialisation advisory Ingeneus Solutions Pty Ltd and former CEO Eustralis Pharmaceuticals Ltd, CEO Immuron Ltd, COO OBI Ltd, GM Holista CollTech Ltd, and CMO Chemeq Ltd.

Investment Summary



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