



# BARD1

LIFE SCIENCES LIMITED

Early cancer detection to save lives

AGM PRESENTATION  
14 November 2019

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# Company Overview

- Medtech company developing non-invasive **cancer diagnostics** to save lives
- **Patented biomarker platform** covering BARD1 biomarkers and applications
- Targeting **unmet needs for early cancer detection** with large market opportunities
- **Pipeline** of screening tests for ovarian, breast and lung cancers
- Compelling results demonstrating **high accuracy and low false positives**
- Focus on **accelerating development** of BARD1-Ovarian towards commercialisation
- **Acquisitive growth strategy** targeting complementary assets to expand Dx portfolio
- **Leadership** with healthcare experience to drive commercialisation and growth

# FY19 Highlights

## Research & Development

- **Progressed Assay Development Program** to transfer BARD1 assay to Luminex platform
- **Advanced Ovarian Cancer Program** with OC-R001 study showing high accuracy with 89% sensitivity and 97% specificity in high-risk women
- **Initiated new Breast Cancer Program** with BC-001 study showing 70% sensitivity and 88% specificity in average-risk women
- **Completed Cancer Vaccine Collaboration** with exploratory studies showing promising results in malignant mesothelioma mouse model
- **5 new patents granted** across 4 patent families in US, Europe, China and Hong Kong

## Corporate & Operational

- **Commenced recruitment** of additional staff to accelerate research projects and implement technology transfer
- **Strengthened Board and shareholder base** with 2 new healthcare experienced directors to guide commercialisation and growth

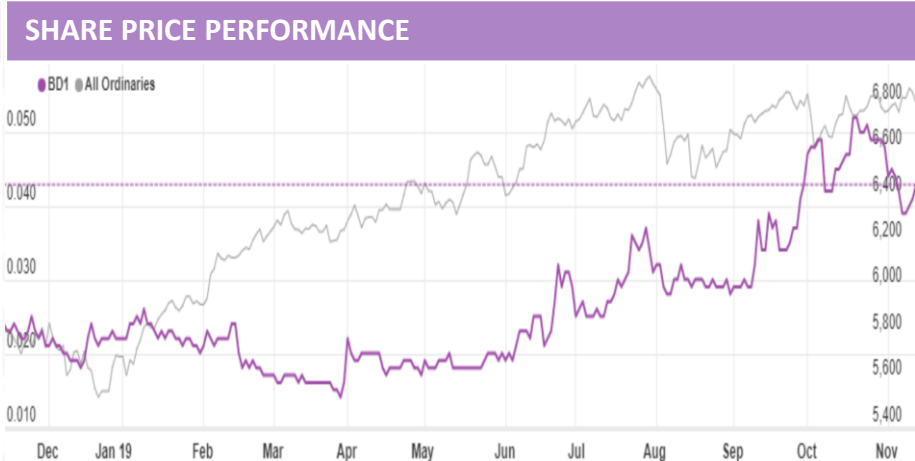
## Financial

- **Capital raisings of \$10.8m** to fund Company's growth strategy
- **Operating expenses** of \$2.3m (2018: \$2.2m)
- **Net loss** for the year of \$1.7m (2018: \$1.8m)
- **Cash balance** at 30/6/19 of \$7.6m (2018: \$1.4m ) & \$10.1m at 12/7/19

# Snapshot

FINANCIAL INFORMATION	ASX:BD1	TOP SHAREHOLDERS (13/11/19)	# SHARES	% HOLDING
Ordinary Shares	1,367.2m	HSBC Custody Nominees (AU) Ltd	125,065,718	9.15%
Market Capitalisation (@13/11/19)	A\$58.8m	Irmgard Irminger-Finger	122,652,337	8.97%
Share Price (@13/11/19)	A\$0.043	The Trust Company Australia Ltd	100,000,000	7.31%
52w H/L Range	A\$0.056-0.014	Moggs Creek Pty Ltd	81,000,000	5.92%
Cash (@30/9/19)	A\$9.3m	Peter Gunzburg	39,382,206	2.88%
Average Daily Volume (3mo)	7.5m	<b>Top 20 Holders</b>	<b>631,496,290</b>	<b>46.19%</b>

BOARD & MANAGEMENT
PETER GUNZBURG   <a href="#">Chairman</a>
DR IRMGARD IRMINGER-FINGER   <a href="#">Executive Director &amp; Chief Scientific Officer</a>
MAX JOHNSTON   <a href="#">Non-Executive Director</a>
PHILIP POWELL   <a href="#">Non-Executive Director</a>
DR LEEARNE HINCH   <a href="#">Chief Executive Officer</a>



# Strategy Update

## Research

- Focus on Dx applications for **unmet medical needs**
- **Prioritise ovarian and breast cancer** applications to take advantage of synergies in high-risk women with HBOC\*
- **Expand BARD1 platform** across other cancer indications and applications
- **Evaluate NEW Dx technologies** to broaden pipeline

## Growth

- Planned expansion of **management team** and relocation to east coast
- **Acquisitive growth strategy** targeting complementary assets to expand Dx portfolio across prediction, screening, diagnosis, CDx & monitoring of cancer
- Vision to **build a leading diagnostics company** with marketed diagnostics and a broad pipeline

## Product Development

- **Technology transfer** to scalable instrument platform to enable ongoing development at Australian operations
- Focus on **accelerating development** of BARD1-Ovarian towards commercialisation
- **Clinical testing** planned to demonstrate clinical sensitivity and specificity in patient population

## Commercialisation

- Initial launch as **Laboratory Developed Tests (LDT)** with certified laboratory partners in AU/US to achieve early revenues and gain real-world product validation
- Full commercialisation as **In Vitro Diagnostic (IVD)** tests partnering with key labs/distributors globally to drive clinical adoption
- Products to be initially offered as user-pays whilst building **reimbursement** case with public and private payers

\*Hereditary Breast and Ovarian Cancer (HBOC) syndrome

# Targeting unmet needs for early detection of cancer

Global cancer burden 18.1m new cases & 9.6m deaths pa<sup>1</sup>

## Ovarian cancer

Deadliest gynaecological cancer

295k new cases

184,799 deaths

## Breast cancer

Most common female cancer

2.1m new cases

626,679 deaths

## Lung cancer

World's deadliest cancer

2.1m new cases

1.76m deaths

## Early detection increases survival

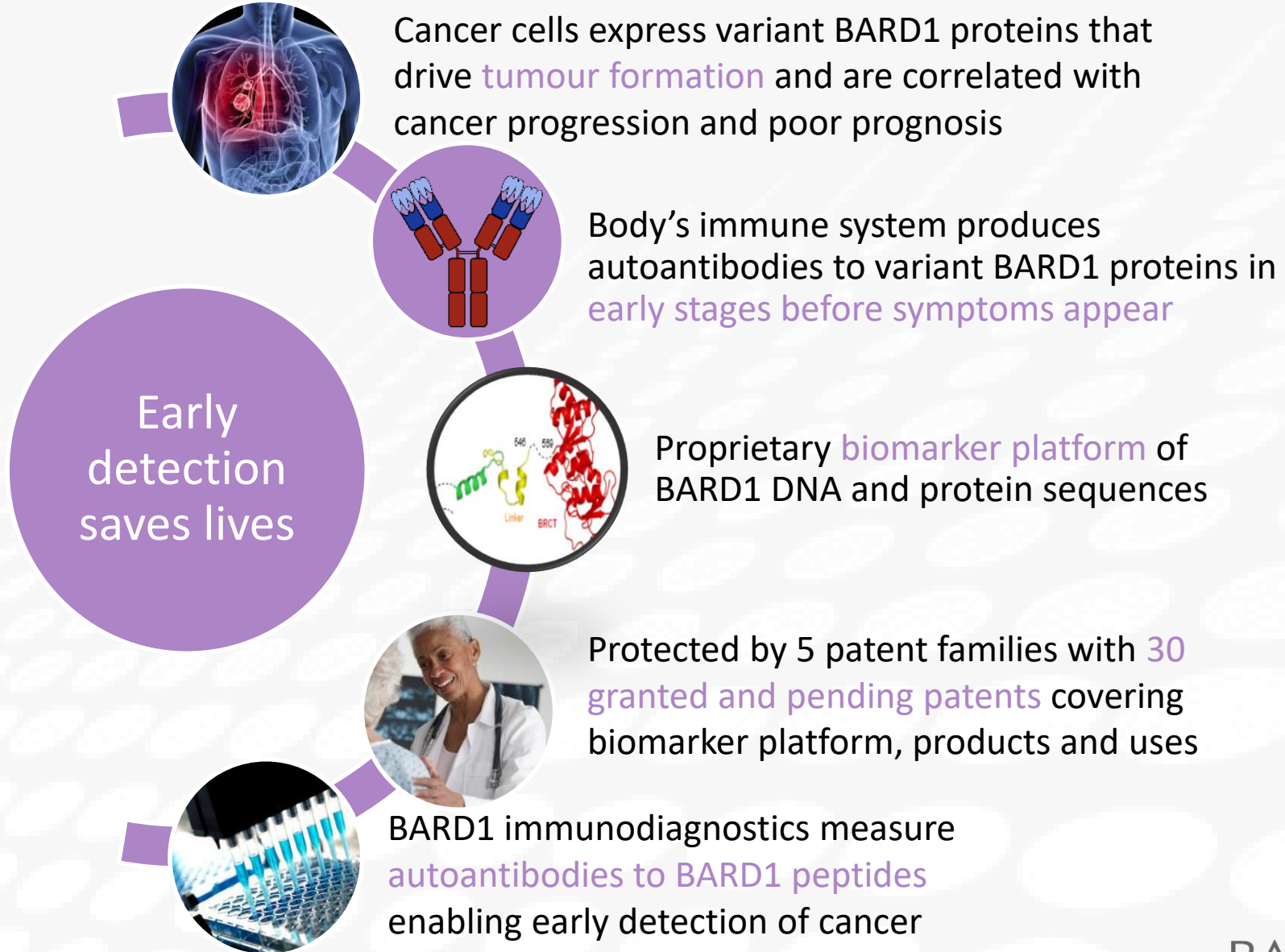
5-year survival	Average	Stage 1	Screening	% uptake
Ovarian	47%	89%	-	0%
Breast	90%	99%	Mammogram	>70%
Lung	19%	55%	LDCT	<3.9%

Current diagnostic methods are limited by cost, accuracy, convenience and access or eligibility to screening programs

## No blood tests approved for screening

Application	Global		USA						
	Incidence	Deaths	Incidence	Deaths	Women 50-74y <sup>2</sup>	Eligible smokers 55-77y <sup>3</sup>	Screening period	Ave price/test	Market Potential <sup>4</sup>
Ovarian Cancer	295k	185k	22.5k	14k	48.4m		Annual	\$ 50	\$2420m
Breast Cancer	2.1m	627k	269m	42k	48.4m		Biennial	\$ 100	\$2420m
Lung Cancer	2.1m	1.8m	228m	143k		6.8m	Annual	\$ 255	\$1734m
<b>TOTAL</b>									<b>\$6574m</b>

# BARD1 biomarker platform and science





# BARD1 Pipeline Development Plan

- 1** Focus on accelerating development of lead product BARD1-Ovarian test
- 2** Assay transfer to Luminex platform achieved with v1 RUO BARD1 kits validated
- 3** Optimisation phase commenced to improve performance of v2 RUO kit and accuracy of BARD1-Ovarian test across OC, controls and non-OC

Calendar Year	2019		2020		2021		2022
	1H	2H	1H	2H	1H	2H	
<b>BARD1 Ovarian</b>	Assay Development		Optimisation		Clinical		Launch
<b>BARD1 Breast</b>			High risk	Evaluation	Optimisation		Clinical → Launch
<b>BARD1 Lung</b>				Evaluation		Assay Development	Optimisation

- 6** Plans to advance pipeline BARD1 tests on same Luminex platform for breast and lung cancers
- 4** BARD1-Ovarian test clinical validation to demonstrate clinical performance
- 5** Launch test initially as LDT with certified clinical laboratory partners

Timelines subject to change according to results, clinical and regulatory advice

# FY20 Catalysts & Plans

## Research & Development

- ✓ Achieved Assay Transfer to Luminex platform with validated v1 RUO kit (4Q CY19)
- ✓ Commenced Optimisation of v2 RUO BARD1 kit(4Q CY19)
  - Commence Optimisation of BARD1-Ovarian test (1H CY20)
  - Commence evaluation of BARD1-Breast cancer test in high-risk women (1H CY20)
  - Commence evaluation of BARD1-Breast and BARD1-Lung cancer tests on Luminex platform (2H CY20)
  - Additional patents and publications to protect and promote BARD1 science

## Operational / Corporate

- Expand management team (1H20)
- Relocation to East Coast (1H20)

# Investment Summary: Building a leading cancer diagnostics company

## Large Market Opportunity

Targeting market opportunity of over US\$6B for unmet needs in early detection of cancer

## Compelling Results

Strong initial results for early detection of ovarian, breast and lung cancers with high accuracy and low false positives

## Accelerating Development

Optimisation and validation studies planned to accelerate development of BARD1-Ovarian then other tests on Luminex platform in Australia

## Focused Commercialisation

Commercialisation focused on partnering LDTs with clinical laboratories and future IVDs with specialist diagnostic distributors

## Acquisitive Growth

Building diagnostics portfolio through internal development and acquisition of complementary assets

## Experienced Leadership

Leadership team with successful track record in the healthcare industry to drive development and commercialisation

## Strong Newsflow

Multiple catalysts expected over next 12 months

# BARD1

## Contacts

**BARD1 Life Sciences Ltd**

Ground, Tempo Building, 431 Roberts Rd  
Subiaco WA 6008 Australia

**P** +61 8 9381 9550 | **E** [info@bard1.com](mailto:info@bard1.com) | **W** [www.bard1.com](http://www.bard1.com)

**Dr Leearne Hinch | CEO**

**E** [leearne@bard1.com](mailto:leearne@bard1.com)

**M** 0400414416

# Healthcare experienced leadership

**PETER GUNZBURG** | Chairman

Public company director and stockbroker with strong corporate, capital raising and stockbroking experience. Previously Director of Australian Stock Exchange Ltd, CIBC World Markets Australia Ltd, Eyres Reed Ltd and several ASX-listed companies.

**DR IRMGARD IRMINGER-FINGER MSc 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, BRCA1 and BARD1 genes with over 90 publications, multiple patents, international collaborations and keynote conference presentations. Former Adjunct Prof at UWA, Privat Docent at UNIGE and Executive Director BARD1AG SA.

**MAX JOHNSTON** | Non-Executive Director

Healthcare industry director and international business leader with extensive experience across medtech, pharmaceuticals, consumer healthcare and consumer goods. Currently Non-Executive Director of PolyNovo Ltd, Medical Developments International Ltd, CannPal Ltd and ProLife Foods NZ. Previously President and CEO of Johnson & Johnson Pacific (division of world's largest medical, pharmaceutical and consumer healthcare company), senior roles at Diageo and Unilever, and past President of ACCORD Australasia Ltd, Vice Chairman of the Australian Food and Grocery Council and board member of ASMI.

**PHILIP POWELL** | Non-Executive Director

Healthcare industry director and chartered accountant with extensive investment banking experience specialising in capital raisings, initial public offerings (IPOs), mergers and acquisitions and other transactions across pharma, food, agriculture and other sectors. Currently Non-Executive Director of PolyNovo Ltd, Medical Developments International Ltd, RMA Global Ltd and alternate Director of Nature's Dairy Australia. Previously held senior financial roles at OAMPS Ltd and audit with Arthur Andersen & Co.

**DR LEEARNE HINCH BVMS MBA** | Chief Executive Officer

Biotechnology CEO, director and consultant with business leadership, strategic, operational, fundraising, business development and commercial experience across diagnostics, devices, therapeutics and animal health. Previously Director Ingeneus Solutions, CEO Eustralis Pharmaceuticals Ltd, CEO Immuron Ltd, COO OBJ Ltd, GM Holista CollTech Ltd, CMO Chemeq Ltd and senior roles in animal health multinationals.

# BARD1's Intellectual Property Portfolio

- 5 patent families protecting biomarker technology platform, products & uses
- Claims covering various BARD1 DNA & protein sequences, methods of diagnosis and treatment, and use in multiple cancers

Patent Family 5	Title	Granted 13	Pending 17	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, EP, JP, JP div, CN, CN div, HK, IL, AU	US divisional, CA, BR, SG	2031*
PCT/IB2011/054194	Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof	US	US divisional, 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	US continuation	2035*

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