

# BARD1

#### LIFE SCIENCES LIMITED

#### Transforming early cancer detection & prevention

AGM PRESENTATION 28 November 2017

#### Forward Looking Statements

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## BARD1 Life Sciences (ASX:BD1)

- Medtech company focused on developing non-invasive diagnostics for early detection of cancer to save patients' lives
- Platform technology of BARD1 tumour markers with potential Dx and Rx applications across multiple cancers
- Diagnostic tests in development for lung and ovarian cancers
- Cancer vaccine project at research-stage
- Pilot studies demonstrating accuracy of BARD1 autoantibody panels for detection of lung and ovarian cancers with high sensitivity and specificity
- Planned studies to further develop and validate the performance of BARD1 Tests
- Large market opportunities and diversified risk across 3 programs

#### Transforming early cancer detection and prevention BARD1 BARD1 BARD1

Ovarian

#### **Company Snapshot**

CORPORATE INFORMATION		SHAREHOLDERS (@ 24/11/17)	# SHARES	% HOLDING
Listed	20 June 2016	Irmgard Irminger*	108,252,420	14.59%
Industry	Biotechnology	Tony Walker*	88,501,626	11.93%
Products	Cancer diagnostics	Peter Lynton Gunzburg	29,835,004	4.02%
Headquarters	Perth, Australia	Universite de Geneve*	12,500,000	1.68%
Ticker	ASX:BD1	Vendor Shares*	229,503,236	30.93%
Ordinary Shares	742m	Top 20 Holders	391,324,085	52.74%
Market Cap (@24/11/17)	A\$5.94m	TOTAL	741,995,731	100.00%
Share Price (@24/11/17)	A\$0.008	*Escrowed until 20/6/18		
52w H/L Range	A\$0.064-0.007			
Cash (@ 30/9/17)	A\$1.71m			
	High: 0.064			
				0.06



## FY2017 Highlights

Financial Results	FY2017 (AUD)
Revenue & other income	\$44,028
Operating expenses	\$2,218,320
Other non-cash expenses	\$129,879
Net Loss before and after tax	\$2,604,171
Loss per share (cps)	0.45
Cash balance @ 30/6/17	\$650,051

**Contracted MSD for assay feasibility** 

Signed LC Diagnostic collaboration with

22/09/16

Oct

on multiplex platform

BARD1 lists on ASX & raises \$3M

UNIGE

01/08/16

15/07/16

Aug

20/06/16

2016

Jun





07/11/16

Dec



## **Platform Technology**

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



BARD1 Technology has potential applications as *diagnostic markers* & *therapeutic targets* for the diagnosis and treatment of various cancers



#### **Development Pipeline**

Pipeline of BARD1 diagnostics and therapeutics in development to diversify product risk and expand market opportunities



UTICS	PRODUCT	INDICATION	RESEARCH	PRE- CLINICAL	PHASE I	PHASE II	PHASE III	APPROVAL
HERAPE	BARD1 Vaccine	Cancer						



## **BARD1** Diagnostics

- BARD1 autoantibody (AAb) tests detect BARD1 AAbs against BARD1 isoforms in human blood
- BARD1 algorithm combines multiple AAb measurements into a cancer score that identifies the presence or absence of a specific cancer



#### Lung Cancer

#### Lung Cancer is the leading cause of cancer deaths worldwide

- □ World: 1.82m new cases & 1.59m deaths pa
- US: 222,500 new cases & 155,870 deaths pa
- **Smoking** is major risk factor in 85% cases
- Poor overall 5-year survival of 18% since 80% diagnosed at late-stage
- Early-detection saves lives increasing survival to over 49%
- Current Dx: chest X-ray → CT scan → bronchoscopy, MRI/PET imaging → biopsy
  - Inaccurate, expensive, invasive or radiation exposure
  - Annual CT screening <u>recommended</u> in high-risk asymptomatic adults aged 55-80 years with >30 pack-year smoking history (USPSTF 2014)



Source: https://www.cancer.org/cancer/non-small-cell-lung-cancer/detection-diagnosisstaging/survival-rates.html

Unmet need for simple, accurate & affordable blood test for early detection

## **BARD1 Lung Cancer Test**

## BARD1 Lung Cancer Test is an ELISA-based blood test in development for early detection of lung cancer

 Pilot studies completed showing high accuracy for detection of lung cancer with up to 80% sensitivity & 77% specificity, and promising results for gender-specific algorithms

Study	n	Model AUC	Test AUC	Sensitivity	Specificity
LC POC	187	0.96	0.86	80%	77%
LC 600	628	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.

- Assay Development planned for 2H18 to further develop, optimise and technically validate the test on a commercial platform
- Clinical Validation required to demonstrate clinical performance for intended use
  - Risk assessment of malignancy in patients with <u>indeterminate</u> <u>pulmonary nodules</u> following CT
  - Screening test for early detection of lung cancer in <u>high-risk</u> asymptomatic individuals





#### **Ovarian Cancer**

## Ovarian Cancer is the leading cause of gynecological cancer deaths

- World: 239K new cases & 152K deaths pa
- US: 22,440 new cases & 14,080 deaths pa
- Highest risk in post-menopausal women over 50 years & hereditary predisposition
- Low overall 5-year survival of 46% since 61% diagnosed at late-stage
- Early-detection saves lives increasing survival to over 90%
- Current Dx: pelvic exam + TVUS → CA125, ROCA or OVA1 blood tests → CT/MRI/PET imaging → Sx biopsy
  - □ Inaccurate, unreliable, expensive or invasive
  - Annual screening <u>not recommended</u> in averagerisk asymptomatic women (USPSTF 2012)

#### Ovarian Cancer 5-Year Survival Rates



Source: www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survivalrates.html

Unmet need for simple, accurate & affordable blood test for early detection

#### **BARD1** Ovarian Cancer Test

#### BARD1 Ovarian Cancer Test is an ELISA-based blood test in development for early detection of ovarian cancer

Pilot studies completed showing high accuracy for detection of ovarian cancer with up to 92% sensitivity & 84% specificity

Study	n	Model AUC	Test AUC	Sensitivity	Specificity
OC POC 1	116	0.86	0.75	68%	65%
OC POC 2	88	0.96	0.89	92%	84%
OC 300	348	0.92	0.85	78%	78%

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.

- **OC400 study** commenced in 400 OC & healthy controls to optimise BARD1 panel & algorithm with results expected Dec-17
- Assay Development planned for 1H18 to standardise and validate technical performance of the test on a commercial platform
- Clinical Validation required to demonstrate clinical performance for intended use in **risk assessment** or **screening**







#### BARD1 Research





#### Global cancer vaccines market US\$3.5B<sup>5</sup>

1. Transparency Market Research 2014; 2. Company estimates; 3. ACS 2017; 4. ACS 2015; 5. BCC 2016



#### **Commercialisation Strategy**





Technical Validation on a commercial platform to demonstrate technical performance
Clinical Validation to demonstrate clinical performance
Market first as laboratory developed tests (LDTs), then as invitro diagnostic (IVD) kits in US, EU and elsewhere
Commercialise through partnering LDTs with central laboratories, and IVDs with distributors or trade sale



and anti-tumour activity in animal models
Complete preclinical safety/toxicology studies in animals
Conduct Phase 1 clinical studies in healthy human volunteers in AU, followed by Phase 2a under IND in US
License at early clinical-stage to biopharma partner for upfront fees, milestone payments and royalties

Demonstrate POC of BARD1-specific immune response

#### 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 6	Pending 20	Expiry
PCT/FR01/02731	Truncated BARD1 protein and its diagnostic and therapeutic uses	US, JP		2023*
PCT/IB2011/053635	BARD1 isoforms in lung and colorectal cancer and use thereof	US, JP, CN, AU	US, JP, CN (divisionals), EP, CA, IL, BR, SG	2031*
PCT/IB2011/054194	Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof		US, EP	2032*
PCT/EP2014/073834	Lung Cancer Diagnosis		US, EP, CA, JP, IL, CN, AU, SG, KR	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



## 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, Fleetwood Corporation Ltd, Dragon Mining Ltd, and Newzulu Ltd.



#### DR IRMGARD IRMINGER-FINGER PD 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 Privat Docent at UNIGE and Adjunct Prof at UWA. Former 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.



#### PROF GEOFF LAURENT PhD FRCP(Hon) FRCPath FMedSci | Non-Executive Director

Accomplished organisational leader, thought-leader, scientific editor, advisory board member & award winning respiratory scientist with over 300 peer reviewed publications. Currently Emeritus Professor at UWA, and Scientific Advisor/Consultant at Helmholtz Zentrum München. Previously Director of the Institute for Respiratory Health and Director of the Centre of Cell Therapy & Regenerative Medicine at UWA, Director of Centre for Respiratory Research, Vice-Dean of Enterprise, and Head of Department of Internal Medicine at University College London, and Past President British Association for Lung Research.



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

Biotechnology executive and consultant with extensive leadership, strategy, fundraising, operational, business development and commercial experience. Founder and director of Ingeneus Solutions Pty Ltd delivering commercialisation advice across drugs, devices, diagnostics & animal health. Previously CEO Eustralis Pharmaceuticals Ltd, CEO Immuron Ltd, COO OBJ Ltd, GM Holista CollTech Ltd, and CMO Chemeq Ltd.

## **Anticipated Milestones**

Date (CY)	Events
4Q17	<ul> <li>Results of OC400 Study</li> </ul>
1H18	<ul> <li>Initiate additional development studies for BARD1 Ovarian Cancer Test</li> </ul>
2H18	<ul> <li>Initiate additional development studies for BARD1 Lung Cancer Test</li> </ul>
	<ul> <li>Complete Technical Validation of BARD1 Test</li> </ul>
	$\circ$ Results of Cancer Vaccine animal efficacy studies
2019	$\circ$ Commence first Clinical Validation study for BARD1 Test
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	PARTNERS
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## **Investment Summary**

Compelling Opportunity	Non-invasive cancer diagnostics targeting unmet needs in US\$101B global market
POC Completed	BARD1 autoantibody tests demonstrated as highly sensitive and specific for detection of lung and ovarian cancers
Development Underway	BARD1 Tests undergoing further development and validation for early detection of lung and ovarian cancers
Diagnostic Advantages	Potential to enable earlier treatment, improve patient outcomes, save lives and reduce healthcare costs
Future Pipeline	Additional high-value diagnostic and therapeutic applications under evaluation
Solid IP	Patents covering technology, products and uses extending beyond 2031
Strong Newsflow	Multiple value-adding milestones expected over next 12-18 months





## Contacts

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### Income Statement for year ended 30 June 2017

	30-Jun-17	30-Jun-16
Revenue & other income	44,028	
Employee benefits expense	(701,669)	(13,673)
R&D expense	(1,089,976)	
Patent expenses	(131,187)	
Administration costs	(575,252)	(109,763)
Depreciation expense	(8,008)	(4,253)
Movement in fair value of investments	(8,990)	
Impairment of available assets for sale	(56 <i>,</i> 458)	
Foreign exchange gain/(loss)	13,754	
Share based payments	(25,000)	
Provision for grant repayment	(65,413)	
Listing expense of acquisition of BARD1		(2,463,404)
Loss arising from remeasurement fin liabili	ities	(250,000)
Loss before income tax expense	(2,604,171)	(2,841,093)
Income tax expense	0	0
Loss after income tax expense	(2,604,171)	(2,841,093)



## Balance Statement for year ended 30 June 2017

	30-Jun-17	30-Jun-16
Current Assets		
Cash & cash equivalents	650,051	3,097,751
Trade & other receivables	31,956	76,412
Held for trading assets	16,659	25,649
Total Current Assets	698,666	3,199,812
Non-Current Assets		
Property, plant & equipment		8,008
Financial assets availble for sale	28,230	84,689
Total Non-Current Assets	28,230	92,697
TOTAL ASSETS	726,896	3,292,509
Current Liabilities		
Trade and other payables	422,946	368,977
Provisions	46,013	20,224
Convertible notes		69 <i>,</i> 387
Total Current Liabilities	468,959	458 <i>,</i> 588
TOTAL LIABILITIES	468,959	458 <i>,</i> 588
NET ASSETS	257,937	2,833,921
EQUITY		
Issued capital	6,645,495	6,620,495
Distribution reserve	(309,421)	(309,421)
Foreign exchange translation reserve	(38,085)	(41,272)
Accumulated losses	(6,040,052)	(3,435,881)
TOTAL EQUITY	257,937	2,833,921



## Acronyms

Accuracy	Percentage of true results correctly identified by a diagnostic test
AUC	Area Under the Curve is an index of the accuracy of a diagnostic test to discriminate between diseased and healthy states
Biomarker	Biological marker of disease state
CE Mark	Conformite Européene mark certifying that a product has met EU consumer safety, health or environmental requirements
CLIA	Clinical Laboratory Improvement Amendment of 1988
СТ	Computed Tomography
ELISA	Enzyme-Linked Immunosorbent Assay
FDA	Food and Drug Administration is the US regulatory authority for medical drugs and devices
НВОС	Hereditary breast and ovarian cancer
Incidence	Number of new cases of a disease in a population during a given time period
IND	Investigational New Drug
IVD	In Vitro Diagnostic
IP	Intellectual Property
FL	Full Length
LDT	Laboratory Developed Test
MRI	Magnetic Resonance Imaging
Pack-year	Packs per day x number of years smoking
РСТ	Patent Cooperation Treaty
PET	Positron Emission Tomography
Prevalence	Number of total cases of a disease in a population over a given time period
ROC	Receiver Operating Characteristics
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
Sensitivity	Probability that a diagnostic test will yield a positive result when the disease is present
Specificity	Probability that a diagnostic test will yield a negative result when the disease is absent
TGA	Therapeutic Goods Administration is the Australian agency for evaluation of medical goods
TVUS	Transvaginal Ultrasound