

LIFE SCIENCES LIMITED

Early cancer detection to save lives

ANNUAL GENERAL MEETING
30 November 2018

# Agenda

- AGM
  - ☐ Chairman's Opening
  - ☐ Business of meeting in including resolutions
  - □ Close of AGM
- **■** CEO Presentation
- Questions
- Tea/Coffee



## Annual Report

□ To table and consider the 2018 Annual Report including the Financial Report, Directors' Report and Auditors' Report for the period 1 July 2017 to 30 June 2018

No resolution is required for this item of business



- Adoption of Remuneration Report
  - □ To consider and if thought fit, to pass with or without amendment, as a non-binding advisory ordinary resolution:

#### Resolution 1:

"That for the purposes of section 250R(2) of the Corporations Act and for all other purposes, the Remuneration Report for the Company and its controlled entities for the year ended 30 June 2018 be approved and adopted"



- Re-Election of Dr Irmgard Irminger-Finger
  - □ To consider and if thought fit, to pass with or without amendment, as an **ordinary resolution**:

#### **Resolution 2:**

"That pursuant to, and in accordance with Listing Rule 14.4, article 6.3(b) and 6.3(c) of the Constitution and for all other purposes, Dr Irmgard Irminger-Finger Director retires and, being eligible, is reelected as a Director on the terms and conditions in the Explanatory Memorandum"



- Approval of 10% Placement Capacity
  - □ To consider and if thought fit, to pass with or without amendment, as a special resolution:

#### **Resolution 3:**

"That pursuant to, and in accordance with Listing Rule 7.1A and for all other purposes, Shareholders approve the issue of Equity Securities up to 10% of the issued capital of the Company (at the time of the issue) calculated in accordance with the formula prescribed in Listing Rule 7.1A.2 and on the terms and conditions in the Explanatory Memorandum"



- Ratification of Placement under Listing Rule 7.1
  - □ To consider and if thought fit, to pass with or without amendment, as an ordinary resolution:

#### **Resolution 4:**

"That pursuant to, and in accordance with Listing Rule 7.4 and for all other purposes, Shareholders approve and ratify the prior issue by the Company of 86,666,666 Placement Shares at an issue price of \$0.015 on the terms and conditions in the Explanatory Memorandum"





# **CEO PRESENTATION**



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## **Investment Highlights**

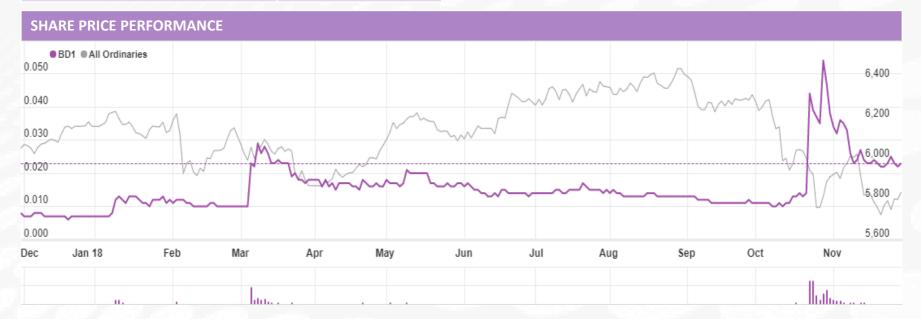
- Medtech company focused on developing non-invasive diagnostics for early detection of cancer to save lives
- Proprietary tumour marker platform with strong IP protecting biomarkers, methods and use
- Targeting unmet needs in burgeoning US\$101B global cancer diagnostics market
- Case-control studies 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<sup>®</sup> 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 for the world's deadliest cancer
- Exploring multiple partnering and corporate opportunities to deliver shareholder value
- Value-adding milestones and newsflow expected in next 6-12 months



# **Corporate Overview**

FINANCIAL INFORMATION	
Ticker	ASX:BD1
Share Price (@29/11/18)	A\$0.023
Ordinary Shares	828.66m
Market Capitalisation (@29/11/18)	A\$19.06m
52w H/L Range	A\$0.075-0.006
Cash (@30/9/18)	A\$1.13m
Average Daily Volume (3mo)	48.60m

TOP SHAREHOLDERS (16/11/18)	# SHARES	% HOLDING
Irmgard Irminger-Finger	108,252,420	13.06%
Peter Gunzburg	29,835,004	3.60%
Tony Walker	26,501,626	3.20%
Universite de Geneve	12,500,000	1.51%
Top 20 Holders	266,489,434	32.16%
TOTAL	828,662,398	100.00%





## 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 Autoantibodies enable early detection of cancers across all stages before symptoms appear

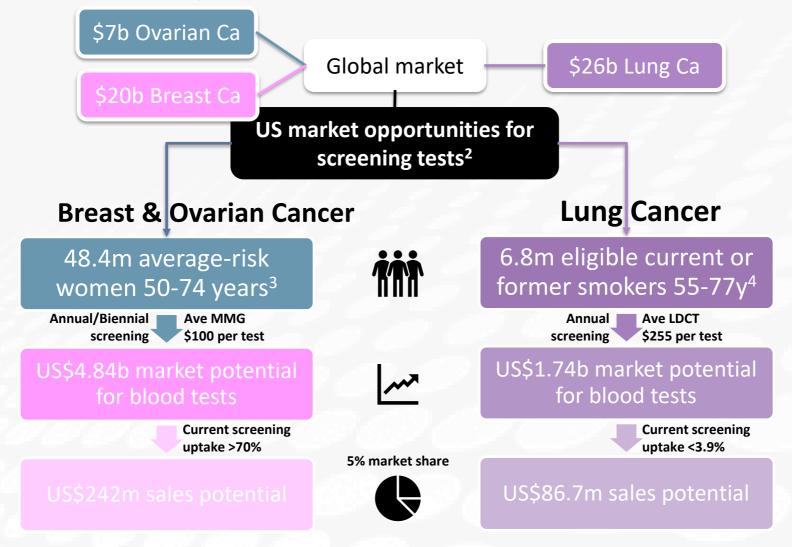
Early detection saves lives Physician ordered blood test with routine blood collection & processing in certified laboratories

Accurate detection of cancer with high sensitivity & specificity

Clinically relevant & actionable results to guide clinical decisions



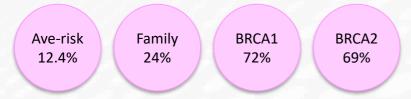
# Focused on unmet needs in Global Cancer Diagnostics Market of US\$101b<sup>1</sup>



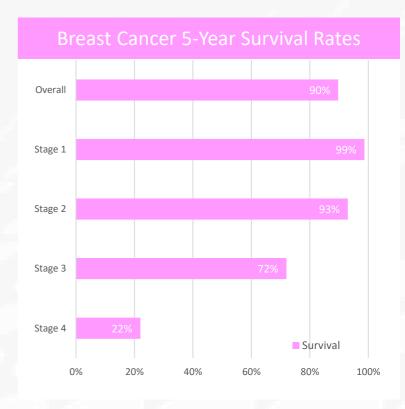


## Breast Cancer is the biggest cancer killer of women

- 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, family history and inherited mutations (BRCA1/2)
- 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

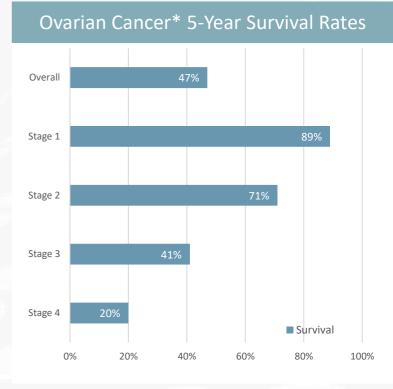


## Ovarian Cancer continues to devastate

- 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, family history and inherited mutations (BRCA1/2)
- 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 for early detection of ovarian cancer across all stages
- 95% accurate 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

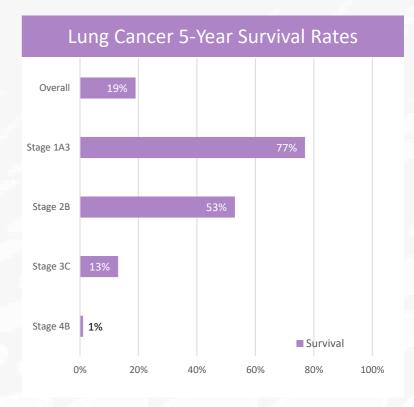
Study	n (cancer:normal)	Model AUC	Test AUC	Sensitivity	Specificity
OC-CA125	400 (200:200)	0.98	0.95	88%	93%
OC-R001	261 (127:134)	0.99	0.97	89%	97%
AUC is the accuracy of the test; Sensitivity is the % of people with cancer that correctly test positive; Specificity is the % people without cancer that 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 screening 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 and smoking
- 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

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:

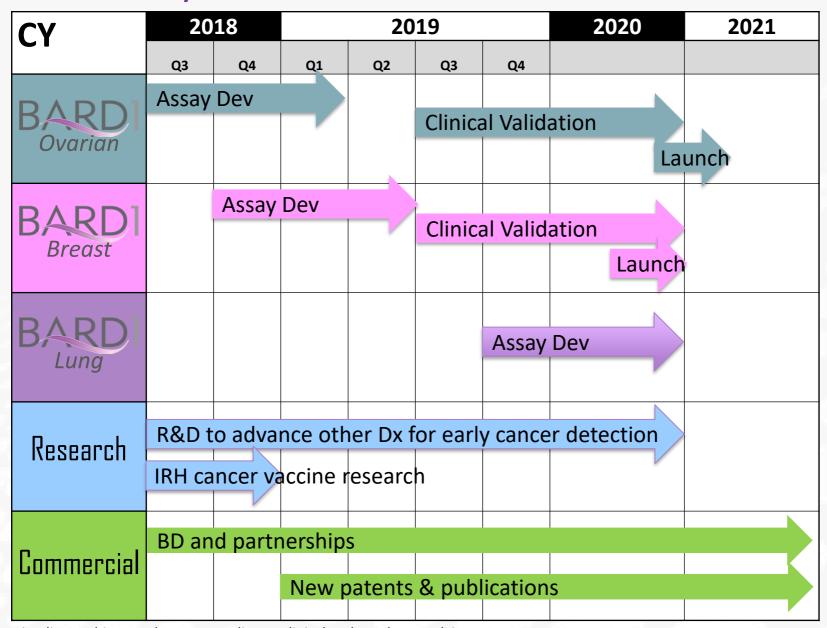
- □ Breast cancer
- □ Tumour inflammatory cell profile
- FINAL RESULTS: Expected Dec-18

#### FUTURE RESEARCH:

- □ Determine methods to improve immune response
- □ Determine effectiveness of BARD1-Vaccine in combination with therapies



## **BARD1** Key Milestones





## **Commercialisation Strategy**

Research

Assay Development Clinical Validation Marketing/ Approval

- ✓ POC studies completed validating biomarker platform in breast, ovarian & lung cancers
- ✓ Multiple case-control studies completed demonstrating high sensitivity & specificity for early detection of cancer
- ✓ Product
  development
  underway to
  standardise BARD1
  autoantibody test on
  Luminex® platform
- planned for 2H19 to demonstrate clinical sensitivity and specificity of both BARD1-Breast and BARD1-Ovarian in patient populations
- Product launch of BARD1-Breast/
  Ovarian anticipated by 1H21
- Market first as
   Laboratory Developed
   Test (LDT) to achieve
   early revenues and
   gain real-world
   product validation
- Secure regulatory approval later as In Vitro Diagnostic (IVD) in US, EU and AU to drive clinical adoption
- Commercialise

   through partnering
   LDTs with certified
   laboratories and IVDs
   with key distributors
   or trade sale



# Significant Achievements 2018

Date	An	nouncements
9/1/18	✓	OC-400 results showing 82% sensitivity & 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 & 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-CA125 results with addition of CA125 showing 88% sensitivity & 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 & 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 & 88% specificity
24/10/18	✓	Chinese Divisional Patent granted covering BARD1-Lung



## Expected newsflow in next 12 months

BARD1-Ovarian

- Complete Assay Development and technical validation on Luminex<sup>®</sup> 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



# Investment Summary: Building a successful Australian diagnostics company

Large Markets	Early cancer diagnostics targeting unmet needs in US\$101B global market
Compelling Results	Industry leading results for early detection of breast, ovarian & lung cancers with high sensitivity & specificity
Development Underway	Assay development on Luminex® platform underway, clinical studies expected to commence in 2H19 and market launch by 1H21
Diagnostic Advantages	Potential to enable earlier treatment, improve patient outcomes, save lives and reduce healthcare costs
Future Pipeline	Pipeline of cancer diagnostics for early detection of other cancers
Solid IP	Granted & pending patents covering biomarkers, methods and uses
Strong Newsflow	Multiple value-adding milestones expected over next 6 - 12 months





# Contacts

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