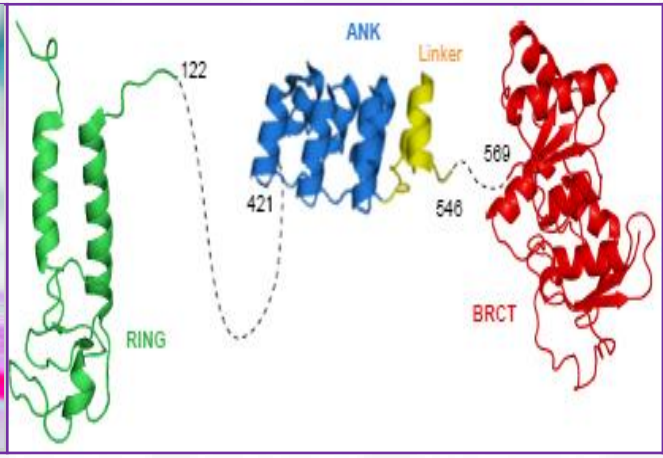
BARD1

LIFE SCIENCES LIMITED

Transforming early cancer detection & prevention



ASX: BD1

AGM PRESENTATION

7th November 2016

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BARD1 Life Sciences (ASX:BD1)

- Life sciences company developing novel diagnostics and therapeutics for unmet needs in cancer
- Leverages proprietary BARD1 technology that is a tumour suppressor in healthy individuals and important tumour biomarker in cancer
- Focused on developing non-invasive diagnostic tests for early detection of cancer in US$100.9B cancer diagnostics market
- Lead product BARD1 Lung Cancer Test is a simple blood test in development for early detection of lung cancer with potential *convenience, accuracy & cost advantages*
- Completed POC Study validating BARD1 antibodies as biomarkers for detection of lung cancer and demonstrating high sensitivity and specificity of prototype BARD1 Test
- Commenced Analytical Validation to further develop, optimise and validate BARD1 Test for early-stage lung cancer on proven ELISA platform
- Planned Clinical Validation studies to prove the safety and performance of BARD1 Test as a screening test for early detection of lung cancer, expected to commence 2H17
- Future pipeline of high-value diagnostics and therapeutics at research-stage for multiple cancers
- Experienced leadership with track record in building successful companies, and international expertise in BARD1 biology, biomarker translation & respiratory medicine

Company Snapshot

Biotech focused on fast-to-market diagnostics with significant upside from potential high-value therapeutic pipeline for unmet needs in cancer

KEY FINANCIALS	
Ticker	ASX:BD1
Ordinary Shares	551,996,586
Performance Shares[1]	217,003,236
Share Price (@4/11/16)	A$0.036
Market Cap (@4/11/16)	A$19.87m
52w Range	A$0.041-0.019
Cash (@ 30/9/16)	A$2.67m

SUBSTANTIAL SHAREHOLDERS	# SHARES	% HOLDING
Irmgard Irminger	108,252,420	19.61%
Tony Walker	88,501,626	16.03%
Paul Sharbanee	33,911,561	6.14%
Peter Lynton Gunzburg	29,835,004	5.40%

1. Escrowed until Jul-18

Leadership Team

Experience & expertise

Peter Gunzburg BCom | Executive Chairman

- Public company director, stockbroker and 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, and internationally recognised expert in BARD1 biology with over 40 publications, 6 issued patents, 30 collaborations and 150 conference presentations
- Currently Privat Docent at UNIGE, Head of the Molecular Gynaecology and Obstetrics Laboratory at HUG, and Adjoint Prof at UWA
- Former Executive Director & founder of BARD1Ag

Brett Montgomery | Non-Executive Director

- Extensive experience in public company management, leadership, corporate governance and risk management
- Currently Non-Executive Director of Tanami Gold NL, and Magnum Gas and Power Ltd
- Previously Managing Director of Kalimantan Gold NL, and Director of 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, and award winning respiratory scientist with over 300 peer reviewed publications
- Currently Director of the Institute for Respiratory Health, and Director of the Centre of Cell Therapy and Regenerative Medicine at UWA
- Former Vice-Dean of Enterprise & Head of Department of Internal Medicine at University College London, Past President of the British Association for Lung Research

Dr Leearne Hinch BSc BVMS MBA | Chief Executive Officer

- Biotechnology executive and consultant with extensive experience in the life science industry in general management, strategy, fundraising, business development and commercialisation
- Currently Director at Ingeneus Solutions
- Previously CEO of Eustralis Pharmaceuticals Ltd and Immuron Ltd, and executive at OBJ Ltd, Holista CollTech Ltd, Chemeq Ltd and Virbac (Australia) Pty Ltd

Business Model

Develop, validate, partner & profit

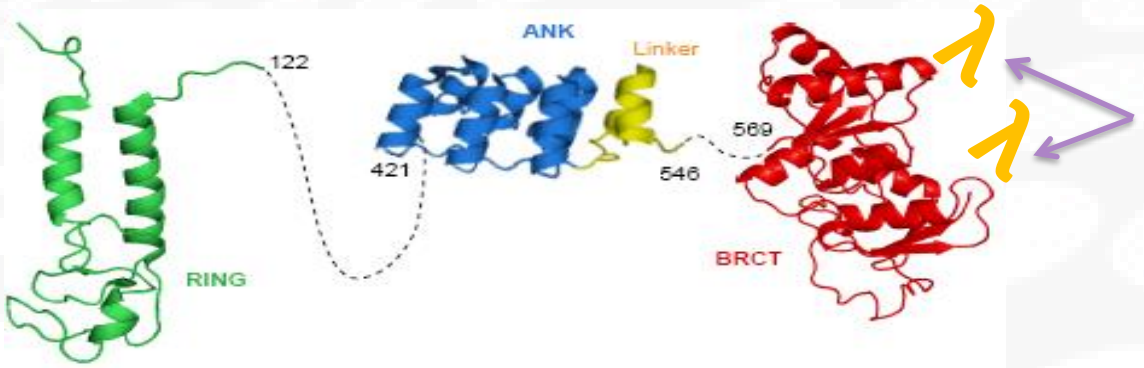
- Focus on developing fast-to-market **diagnostic tests for early detection of cancer** that are reliable, accurate and affordable
- Deliver **clinical evidence** to demonstrate medical value and enable medical device marketing or approval in Europe, Australia & USA
- Commercialise through **licensing** of laboratory tests (LDTs) to central laboratories, or of approved in vitro diagnostics (IVDs) to multinational partners for royalties
- Expand research to develop **high-value therapeutic pipeline** for unmet needs in cancer and partner early to biopharma partner for upfront fees, milestone payments & future royalties
- Create value for ASX:BD1 shareholders

BARD1 Technology

Science

- *BARD1* gene (BRCA1-associated RING domain 1) is a tumour suppressor coding for the **BARD1 protein**
  - BARD1 protein binds & stabilises the BRCA1 protein, otherwise unstable[1]
  - BRCA1 is responsible for DNA repair, whereas BRCA mutations increase the risk for breast cancer
  - BARD1 is important in mitosis and required for cytokinesis, whereas BARD1 depletion leads to cell cycle arrest[2]
- Cancer cells express a number of aberrant **BARD1 isoforms** generated by alternate gene splicing
  - BARD1 isoforms antagonise the functions of 'normal' BARD1 and BRCA1 to drive oncogenesis[3]
  - Different combinations of BARD1 molecules are specific for different cancers[4]
  - BARD1 mutations identified in multiple non-coding & coding regions that predispose to cancer[5]
- BARD1 isoforms have been correlated with cancer progression & poor prognosis[6]
- BARD1 epitopes are **novel and specific biomarkers** for multiple cancers

Normal BARD1



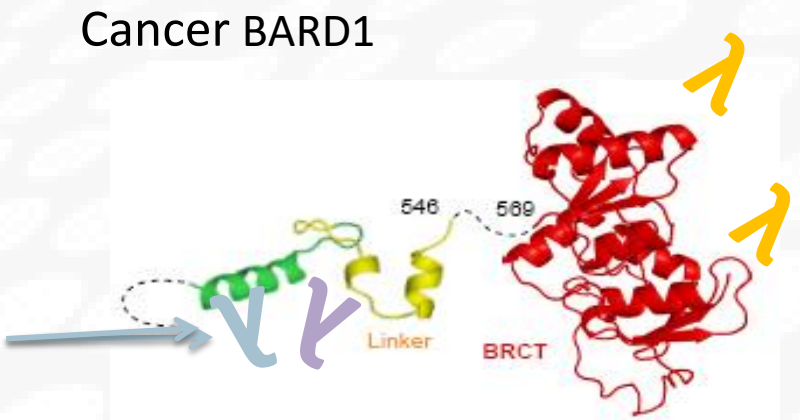
1. Wu et al 1996; Irminger-Finger et al 2016
2. Ryser et al 2009; Zhang et al 2004; Delaval et al 2004; Daniels et al 2004
3. Ryser et al 2009; Bosse et al 2012
4. Wu et al 2006; Li et al 2007; Zhang et al 2012a; Zhang et al 2012b; Lepore et al 2013
5. Nowakowska et al 2015; Ratajska et al 2015
6. Zhang 2012a; Zhang 2012b; Wu et al 2006; Li 2007b

Novel, proprietary & specific cancer biomarkers

Biomarker Translation

Scientific Rationale

- BARD1 is potentially a **diagnostic biomarker and therapeutic target** for cancer
  - Aberrant BARD1 proteins are released in large amounts by cancer cells and induce circulating BARD1 autoantibodies that can be detected early in the blood enabling early diagnosis of cancer[1]
  - BARD1 cancer-specific RNA-isoforms result in diagnostic signatures that can be detected by liquid biopsy methods[1]
  - Cancer-associated BARD1 isoforms can be targeted to inhibit their oncogenic potential enabling targeted therapies for prevention or treatment of cancer
- Potential **applications** for Lung, Breast, Ovarian, Prostate, Colorectal & other cancers
  - Global **cancer diagnostics market** valued at US $100.9B in 2013 & $168.6B by 2020[2]
  - Global **cancer therapeutics market** was valued at US $78.2B in 2013 & $111.9B by 2020[3]



1. Wu et al 2006; Li et al 2007; Zhang et al 2012a; Zhang et al 2012b
2. TMR. Cancer Diagnostics Market. 2014
3. Allied Analytics. Global Oncology Drugs Market. 2015

Pipeline

Balanced risk profile

- Developing a pipeline of cancer diagnostic & therapeutic products based on its proprietary BARD1 technology
- Lead product is BARD1 Lung Cancer Test for early detection of lung cancer
- Research-stage pipeline targeting unmet needs in multiple cancers

DIAGNOSTICS

PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	ANAYTICAL VALIDATION	CLINICAL VALIDATION	MARKETABLE / APPROVAL
BARD1 Lung Cancer Test	Lung Cancer	ELISA[1] (Blood)	Screening & Diagnosis	→	→	2H17	
BARD1 Ovarian Cancer Test	Ovarian Cancer	ELISA (Blood)	Detection & Monitoring	→			
BARD1 RNA Test	Cancer	RT-PCR (Blood)	Diagnosis & Monitoring	→			

THERAPEUTICS

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

[1]ELISA = Enzyme Linked ImmunoSorbent Assay
[2]RT-PCR = Reverse Transcriptase Polymerase Chain Reaction

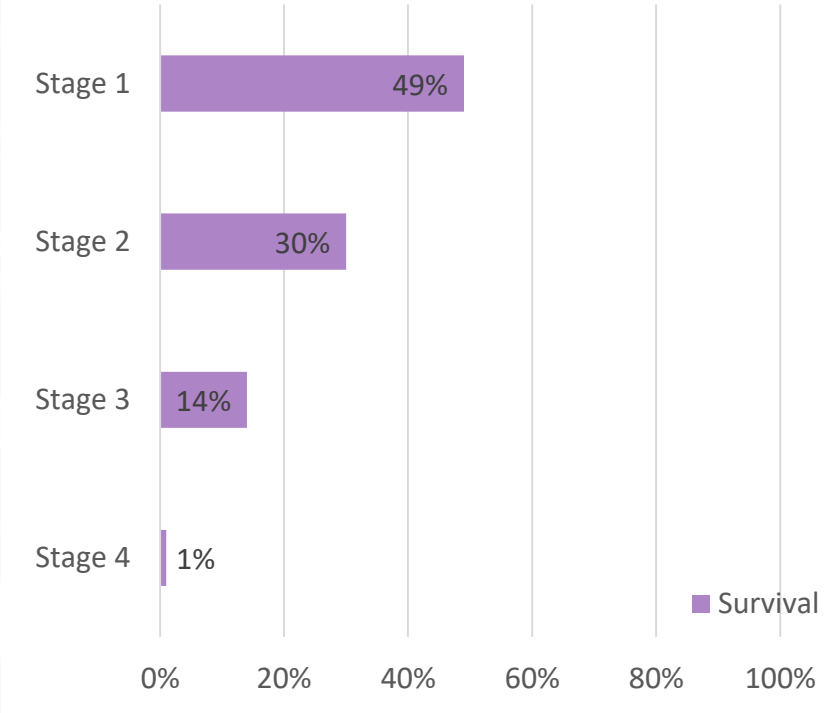
Lung Cancer

Facts

- Lung Cancer is the leading cause of cancer death worldwide[1]
  - Incidence: 1.82m new cases pa
  - Mortality: 1.59m deaths pa
- Cancer types
  - NSCLC (Non-Small Cell Lung Cancer): 85% cases
  - SCLC (Small Cell Lung Cancer): 15% cases
- Risk factors
  - Smoking: 90% cases
  - Other: age (>65y), second-hand smoke, radon exposure, occupational exposure, cancer history, family history, lung disease
- 5-year survival is linked to stage at detection[2]
  - Average 5-year survival 17.4% in US & 5.8% worldwide[1]
  - Late-detection is deadly: majority of patients diagnosed at late-stage with <1% survival
  - Early-detection saves lives: potentially >50% survival rate if diagnosed early
- Early diagnosis is linked to improved prognosis & reduced mortality[2,3]
- Global lung cancer diagnostics market US$26.0B in 2013 & US$42.2B by 2020, with 7.1% CAGR[4]

5-Year Survival Rate by Stage at Detection

It takes 10-20 years for lung cancer symptoms to appear and only 3-4 years for cancer to progress from Stage 1 to 4



1. GLOBOCAN 2012
2. ACS 2016
3. NCI 2014
4. TMR. Cancer Diagnostics Market. 2014

Early detection saves lives!

Lung Cancer

Unmet need for early detection

- **Current diagnostic** options are limited
  - **Chest X-ray:** standard diagnostic tool in symptomatic patients, but not specific for LC
  - **CT scan:** 'gold standard' screening & diagnostic tool, but routine use limited by high false positives, additional diagnostic confirmation, radiation exposure & cost
  - **Biopsy: '**definitive diagnostic' to determine cancer type & stage, but invasive & expensive
  - **No simple blood test currently available**
- **Treatment advances** in surgery, radiotherapy & chemotherapy have not improved Overall Survival
- However, **early diagnosis** has improved 5-year survival
  - Low dose CT screening has shown a reduction in RR of mortality by 20% over chest X-ray[1]
  - Clinical guidelines recommend annual screening for lung cancer with LDCT[2]

NCCN Guidelines recommend "annual screening for lung cancer with low-dose computed tomography (LDCT) in high-risk asymptomatic adults aged 55-74 years with a greater than 30 pack-year smoking history that either continue to smoke or have quit within the past 15 years"

- **Cancer screening** is critical to enable early detection, improve prognosis & help inform treatment options

1. NCI 2014
2. NCCN, Guidelines 2016
3. TMR. Cancer Diagnostics Market. 2014

LC = Lung Cancer
LDCT = Low Dose Computed Tomography
RR = Relative Risk

Unmet need for a non-invasive, simple, accurate & affordable screening test for early detection of lung cancer

BARD1 Lung Cancer Test

Simple, accurate & affordable non-invasive blood test

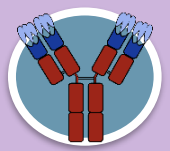
- BARD1 Test is a non-invasive blood test in development for early detection of lung cancer
  - ELISA-assay detecting BARD1 autoantibodies in blood serum
  - BARD1 antibodies detectable from early-stage tumours (improves accuracy for early-stage lung cancer)
  - Specific BARD1 epitopes are used to capture anti-BARD1 antibodies specific for lung cancer
  - Results are measured by electrochemiluminescence (ECL) in a dynamic-range system
  - Meso Scale Diagnostics (MSD) engaged to optimise BARD1 Test on proven instrument platform to enable fast, accurate & reliable testing at low cost
- Intended use
  - **Screening** test for early detection of lung cancer in high-risk asymptomatic individuals
  - **Diagnostic** test for detection of lung cancer in symptomatic patients, or as a diagnostic aid to confirm CT scan
- Parallel development of BARD1 Test for marketing or approval in Europe first then USA may speed development, reduce cost & lower regulatory hurdles
- BARD1 Test offers potential advantages over other methods

Convenient	Simple blood collection, standard lab methods & fast results
Safe	Non-invasive blood test can be repeated regularly & complements other diagnostic methods
Accurate	Expected high sensitivity >90% and false positives <10%
Affordable	Estimated $200 per test

Potential new first-line screening and diagnostic test for lung cancer

Order blood test

Take blood sample (<1mL)



Lab results in 3-5 days

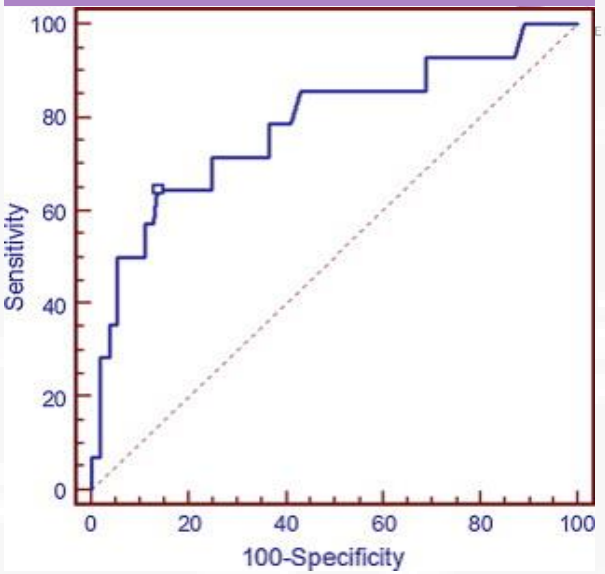
Doctor receives result to inform patient & follow-up

Proof of Concept Study

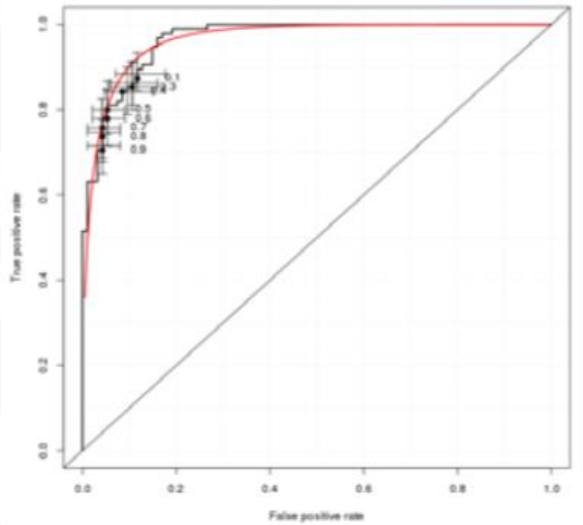
Results

- STUDY DESIGN: Controlled POC study in ~200 samples of lung cancer & healthy controls to determine the utility of circulating BARD1 antibodies as biomarkers for early detection of lung cancer
- RESULTS: BARD1 diagnostic models accurately discriminated lung cancer from healthy controls[1]:
  - Training sets: Average AUC=0.96, Sensitivity >95%, False Positives <5%
  - Validation set: Sensitivity >90%, False Positives <10%
- CONCLUSION: High AUCs demonstrate POC that selected models accurately detect lung cancer with high specificity and sensitivity

Typical ROC curve for CT Scan[2]



ROC curve for BARD1 Test



1. BARD1. Results on file. 2016
2. Hiroaki Nomori et al. 2004

AUC = Area Under Curve
ROC = Receiver Operating Characteristic

BARD1 Test more accurate than current gold standard LDCT

Analytical Validation

Commenced

- CONFIRMATION STUDY: Internal study to further develop & optimise prototype BARD1 Lung Cancer Test in over 450 samples of lung cancer and healthy controls for sensitivity & specificity of lung cancer in multiple cohorts comprising lung cancers of different types and stages, age, gender & ethnicity
- ANALYTICAL VALIDATION STUDY: External study to transfer, optimise & validate the BARD1 Lung Cancer Test on proven instrument platform for reproducibility, repeatability, stability, precision, interference and limits if detection
- RESULTS: expected 1Q17

Clinical Validation

Planned

- PROSPECTIVE CLINICAL STUDY:
  - **Design:** Prospective, multicentre clinical study of ~1000 high-risk asymptomatic adults aged 55-74 years with a 30-pack year smoking history to demonstrate the safety and performance (sensitivity & specificity) of the BARD1 Lung Cancer Test compared to LDCT Scan for early detection of lung cancer
  - **Objective:** Verify that the BARD1 Lung Cancer Test achieves a lung cancer detection rate of greater than 90% and a false positive rate of less than 10%
  - **Commencement:** Expected 2H17
- POST-MARKETING TRIALS:
  - Additional studies may be required to demonstrate the clinical utility (reduced mortality & improved quality of life) and health economic benefits of annual screening with the BARD1 Test compared to LDCT Scan over multiple years

Enable marketing or approval of laboratory tests under CE Mark in EU, ARTG Listing in AU, and CLIA-certified LDT test followed by FDA-cleared IVD in US

Ongoing BARD1 Research

BARD1
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- Advance diagnostic pipeline for multiple cancers
  - Accelerate development of new **Diagnostic Tests** for Ovarian and other cancers
  - Initiate research to develop **Liquid Biopsy** products for diagnosis and treatment monitoring of cancer from blood and/or tissue samples
  - Partner to co-develop **Companion Diagnostics** for patient selection and monitoring of specific cancer treatments
- Progress therapeutic pipeline for BARD1 positive cancers
  - Collaborate to research and evaluate development of targeted **therapies** for prevention or treatment of cancer

Intellectual Property Portfolio

- Strong IP portfolio with 5 patent families covering various BARD1 peptide sequences, methods of diagnosis & treatment, and use in multiple cancers

Patent Family	Title	Status		Expiry
		Granted	Pending	
PCT/FR01/02731	Truncated BARD1 proteins and its diagnostic and therapeutic uses	US, JP		2023
PCT/IB2011/053635	BARD1 isoforms in lung and colorectal cancer and use thereof		US, EP, CA, JP, IL, CN, AU, 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

Future Milestones

Multiple value-adding milestones & newsflow

Events	Date (CY)
Commencement of Analytical Validation studies of BARD1 Lung Cancer Test for Lung Cancer	3Q16
Appointment of CEO	4Q16
Publish POC Study results in international peer-reviewed journal	1Q17
Expand R&D team	1Q17
Results of Analytical Validation studies of additional 450 samples	1Q17
Appoint Advisory Board	1H17
Commence Clinical Validation study of BARD1 Lung Cancer Test for early detection of Lung Cancer	2H17
Preliminary results of Clinical Validation study of BARD1 Lung Cancer Test	2018
CE Mark for marketing of BARD1 Lung Cancer Test in Europe	2019*
ARTG Listing for marketing of BARD1 Lung Cancer Test in Australia	2019*
Marketing of CLIA-certified LDT in USA	2019*

*Regulatory advice being sought on optimal regulatory strategy to firm up timelines

Investment Highlights

Commercially Compelling	Potential cancer diagnostics targeting unmet needs in US$101B global market
Proven Science	Multiple publications validating BARD1 as a potential diagnostic marker & therapeutic target in multiple cancers
POC Completed	BARD1 biomarkers demonstrated as highly sensitive and specific for detection of Lung Cancer
Commenced Validation	BARD1 Lung Cancer Test undergoing validation studies to develop, optimize & clinically validate the test for early detection of lung cancer
Diagnostic Advantages	Non-invasive blood tests for early detection of cancer that are simple, accurate & affordable
Future Pipeline	Additional high-value diagnostic & therapeutic applications being evaluated for development
Solid IP	Broad patents covering technology, products and uses extending to 2035
Experienced Leadership	Scientific, clinical research & commercialisation expertise committed to delivering cancer detection & prevention solutions to improve patients' lives
Strong Newsflow	Multiple milestone announcements & valuation inflection points over next 12-24 months

Contact details

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Acronyms

AUC	Area Under the Curve is an index of the accuracy of a diagnostic test to discriminate between diseased and healthy states
Biomarker	Serum marker of disease state
CE Mark	Communaute/Conformite European mark certifying that a product has met EU consumer safety, health or environmental requirements
CLIA	Clinical Laboratory Improvement Amendment of 1988
CMC	Chemistry, Manufacturing & Controls
CRO	Contract Research Organisation
ctDNA	Circulating tumour DNA in a Liquid Biopsy test
ELISA	Enzyme-Linked Immunosorbent Assay
FDA	Food and Drug Administration is the US regulatory authority for medical drugs and devices
Incidence	Number of new cases of a disease in a population during a given time period
IVD	In Vitro Diagnostic
IP	Intellectual Property
LDCT	Low Dose Computed Tomography
LDT	Laboratory Developed Test
PCT	Patent Cooperation Treaty
Prevalence	Number of total cases of a disease in a population over a given time period
QOL	Quality of Life
ROC	Receiver Operating Characteristics
RR	Relative Risk
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
TGA	Therapeutic Goods Administration is the Australian agency for evaluation of medical goods