

## **BARD1 RELEASES CORPORATE PRESENTATION**

**Perth, Australia, 22 March 2018:** BARD1 Life Sciences Limited (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, is pleased to release to shareholders and investors its latest Corporate Presentation providing an overview of the Company, its technology, pipeline and commercialisation strategy.

A copy of the corporate presentation is appended to this announcement.

- ENDS -

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### **ABOUT BARD1 LIFE SCIENCES LTD**

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian-based biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. BARD1's proprietary technology platform is based on novel tumour markers with potential diagnostic and therapeutic applications across multiple cancers. The development pipeline includes two BARD1 autoantibody tests in early development for early detection of lung and ovarian cancers, and a cancer vaccine project at research-stage for treatment of cancer. Additional diagnostic projects are being evaluated for prostate, breast and other cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients' lives. For more information on BARD1, see [www.bard1.com](http://www.bard1.com).



# BARD1

LIFE SCIENCES LIMITED

Transforming early cancer detection & prevention

CORPORATE PRESENTATION

March 2018

# 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**  
*Lung*

**BARD1**  
*Ovarian*

**BARD1**  
*Vaccine*

# Company Snapshot

CORPORATE INFORMATION	
Listed	20 June 2016
Industry	Biotechnology
Products	Cancer diagnostics
Headquarters	Perth, Australia
Ticker	ASX:BD1
Ordinary Shares	742m
Market Cap (@13/3/18)	A\$19.29m
Share Price (@13/3/18)	A\$0.026
52w H/L Range	A\$0.064-0.006
Cash (@31/12/17)	A\$1.2m

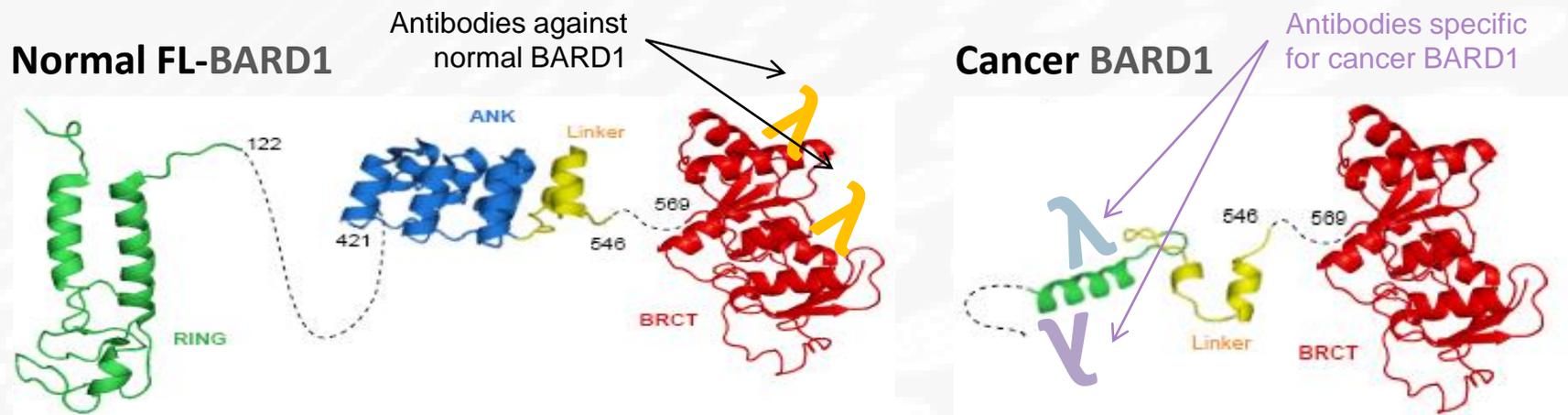
SHAREHOLDERS (@ 31/12/17)	# SHARES	% HOLDING
Irmgard Irminger*	108,252,420	14.59%
Tony Walker*	88,501,626	11.93%
Peter Lynton Gunzburg	29,835,004	4.02%
Universite de Geneve*	12,500,000	1.68%
<b>Vendor Shares*</b>	<b>229,503,236</b>	<b>30.93%</b>
<b>Top 20 Holders</b>	<b>391,324,085</b>	<b>52.74%</b>
<b>TOTAL</b>	<b>741,995,731</b>	<b>100.00%</b>

\*Escrowed until 20/6/18



# 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

DIAGNOSTICS	PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL VALIDATION	MARKETING / APPROVAL
	<b>BARD1</b> <i>Lung</i>	Lung Cancer	ELISA (Blood)	Screening & Risk Assessment				
	<b>BARD1</b> <i>Ovarian</i>	Ovarian Cancer	ELISA (Blood)	Detection & Monitoring				

THERAPEUTICS	PRODUCT	INDICATION	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	APPROVAL
	<b>BARD1</b> <i>Vaccine</i>	Cancer						

# Large Market Opportunities

■ Global cancer diagnostics market US\$101B<sup>1</sup>

\$24B Lung Ca

\$7B Ovarian Ca

## US market opportunities for screening tests<sup>2</sup>

### Lung Cancer screening test

6.8M eligible current / former smokers 55-77y<sup>3</sup>

Ave reimbursement LDCT \$255 per test

US\$1.74B market potential

US\$86.7M sales potential

### Ovarian Cancer screening test

43.2M average-risk women 50-74 years<sup>4</sup>

Ave \$100 per test x 10% uptake

~US\$432M market potential for blood tests

US\$21.6M sales potential



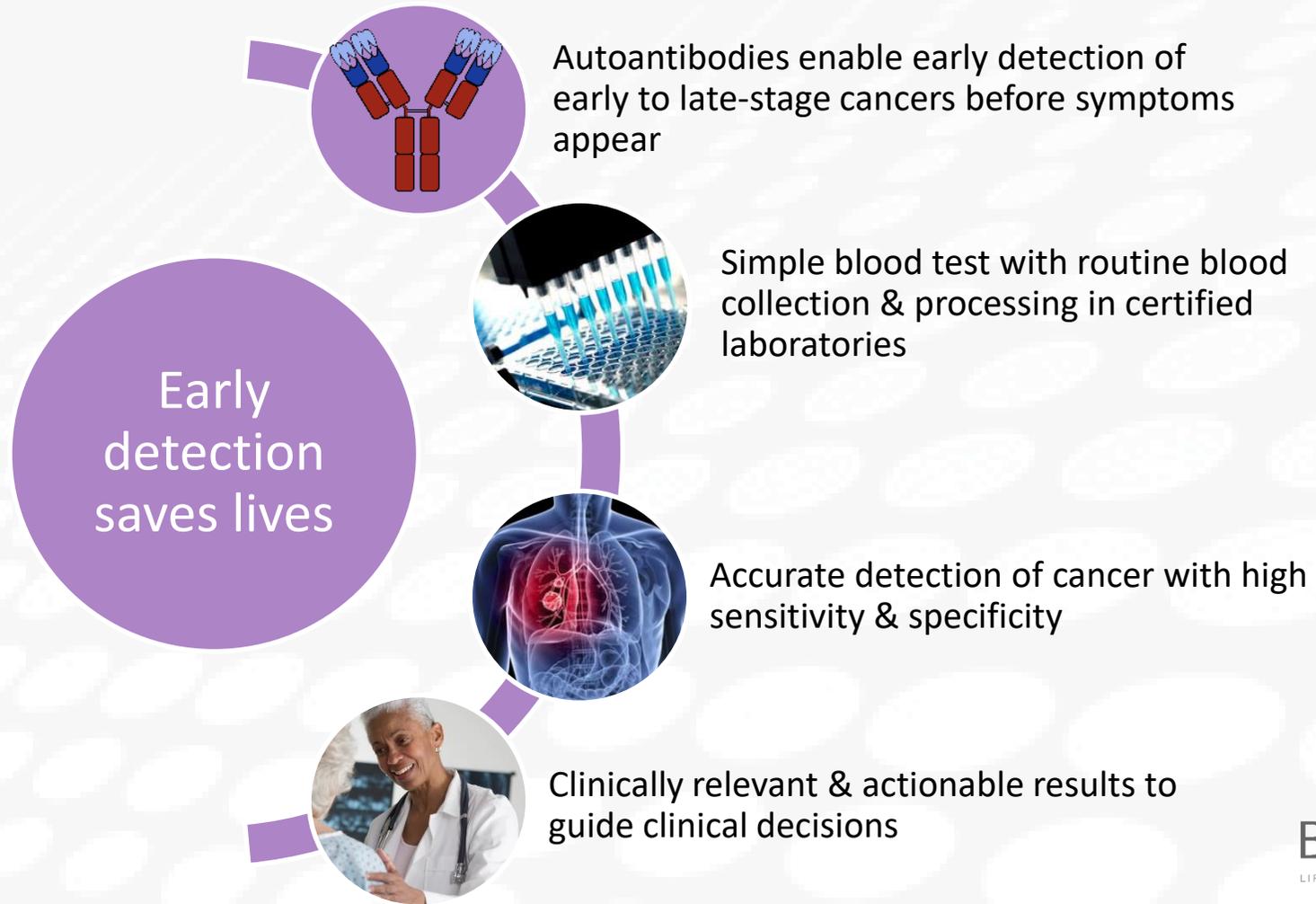
5% market share



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

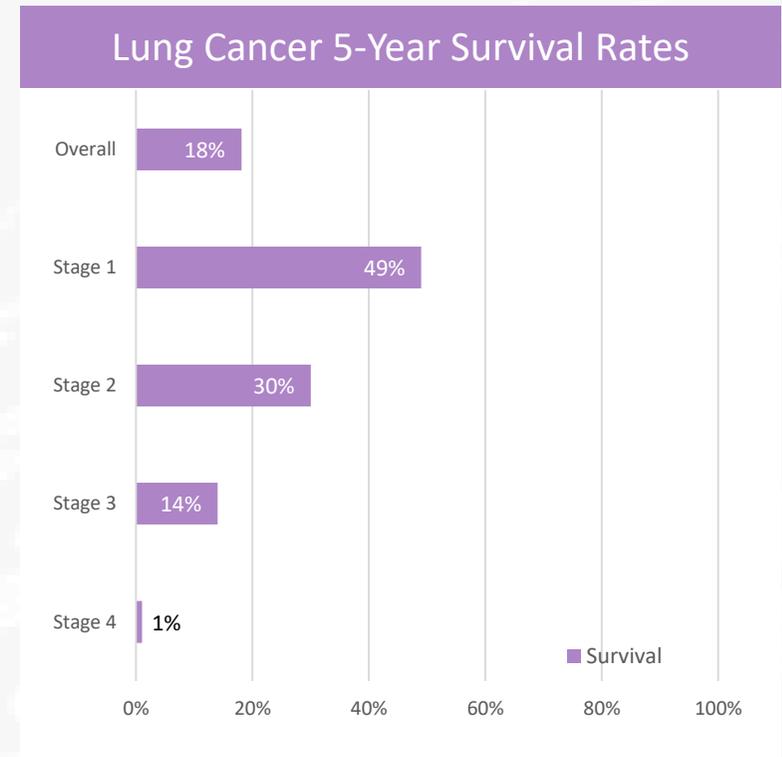
# BARD1 Diagnostics

- 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 recommended 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-diagnosis-staging/survival-rates.html>

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

# BARD1-Lung

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

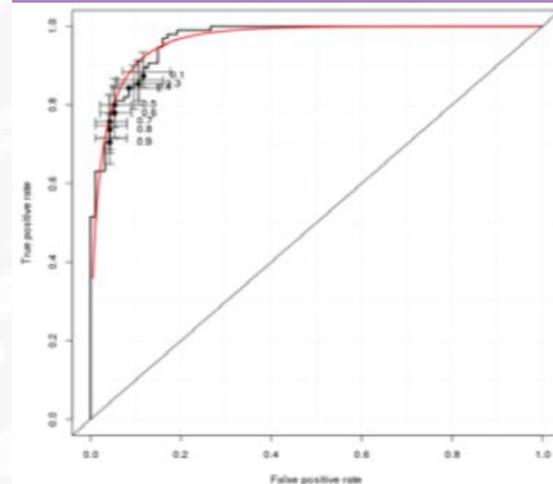
- **Pilot studies** completed showing high accuracy for detection of lung cancer with up to 80% sensitivity & 77% specificity, and promising results for gender-specific algorithms

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.

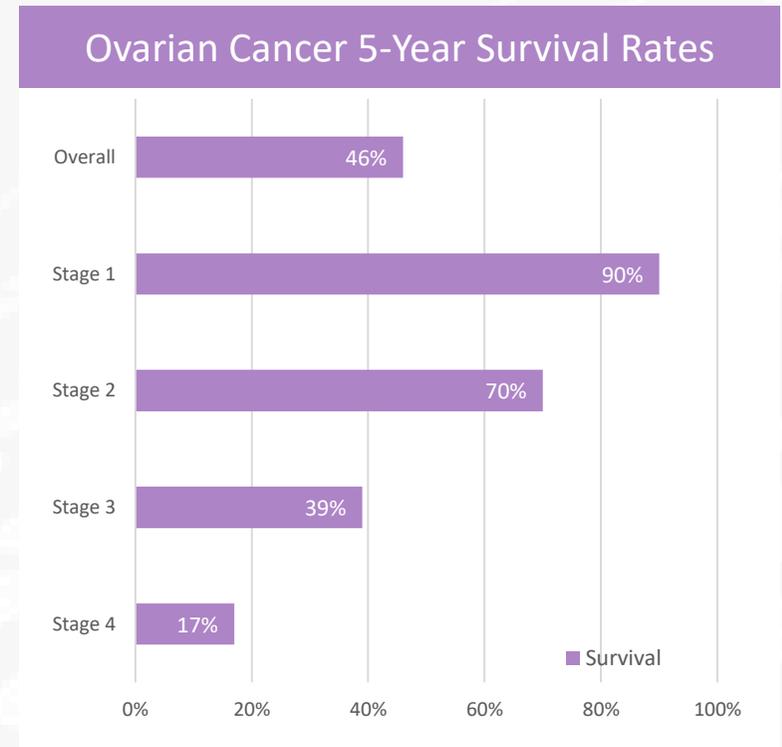
- **Assay Development** planned for 2H18 to further develop, optimise and technically validate the test on a commercial platform
- **Clinical Validation** required to demonstrate clinical performance for intended use
  - **Risk assessment** of malignancy in patients with indeterminate pulmonary nodules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

ROC curve for BARD1-Lung



# 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** & family history
- **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 not recommended in average-risk asymptomatic women (USPSTF 2012)



Source: [www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html](http://www.cancer.org/cancer/ovarian-cancer/detection-diagnosis-staging/survival-rates.html)

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

# BARD1-Ovarian

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

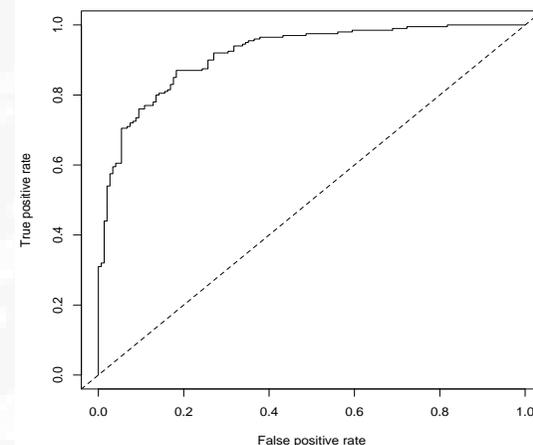
- **Pilot studies** completed showing high accuracy for detection of ovarian cancer with over 82% sensitivity & 79% specificity

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%
OC-400	400	0.92	0.88	82%	79%

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 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**

ROC curve for BARD1-Ovarian



# BARD1 Research



**Dx**

Expand BARD1 **diagnostic** pipeline for other cancers

- Evaluate **BARD1 autoantibody (AAb) tests** for other cancers including prostate & breast cancers
- Investigate **BARD1 RNA test** for prediction of cancer progression in premalignant human specimens

**Rx**

Evaluate BARD1 **therapeutic** applications for cancer

- Entered **cancer vaccine collaboration** with IRH to evaluate a potential BARD1 vaccine for prevention or treatment of cancer in animal models

**CDx**

Explore future opportunities in **companion diagnostics** for patient selection and treatment monitoring

# Commercialisation Strategy

**BARD1**  
*Lung*

**BARD1**  
*Ovarian*

- **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

**BARD1**  
*Vaccine*

- Demonstrate **POC** of BARD1-specific immune response 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

# 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 7	Pending 21	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, JP (div), CN, AU	US, CN (divisionals), EP, CA, IL, BR, SG, HK	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, 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

# Leadership Team

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## **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.

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## **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.

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## **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.

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## **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.

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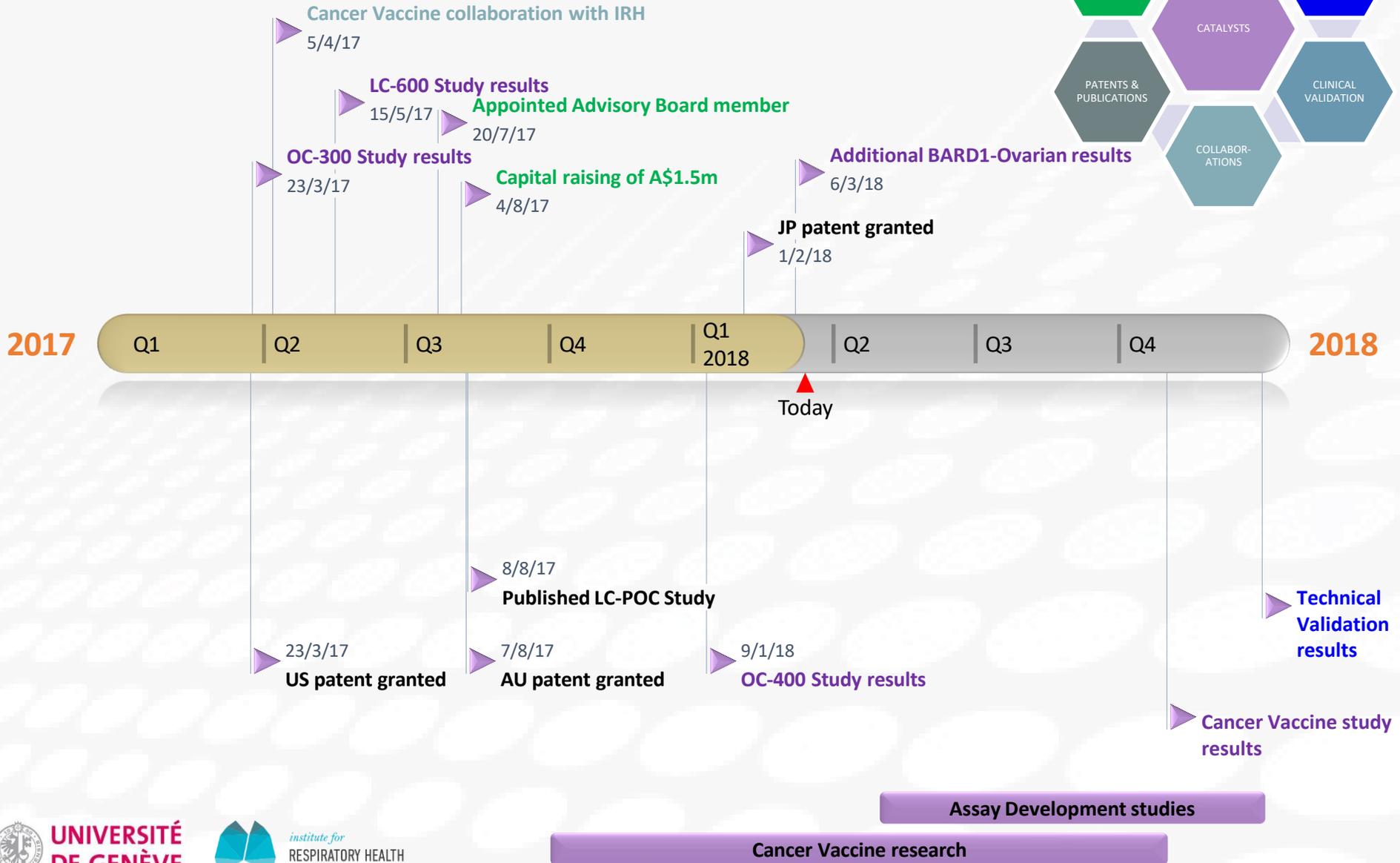
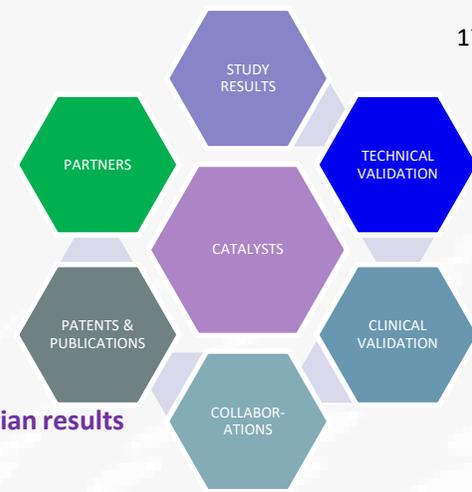


## **DR LEEARNE HINCH** BVMS MBA | Chief Executive Officer

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.

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# Investment Highlights



# 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

# BARD1

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**Dr Learne Hinch | CEO**

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

# 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
CT	Computed Tomography
ELISA	Enzyme-Linked Immunosorbent Assay
FDA	Food and Drug Administration is the US regulatory authority for medical drugs and devices
HBOC	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
PCT	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