



DRIVING A NEW PARADIGM IN
BREAST CANCER DIAGNOSTICS



2 MAY 2024

JMM & ETHICA CAPITAL- Innovation & Investment Insights

Jayne Shaw

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COMPANY METRICS



ASX Code

BDX

Share Price
12 April 2024

\$0.10

Shares on Issue

252M

Unlisted Options

4.5M

Cash
31 March 2024

\$3.3M

Top 20 Shareholders

57%

COMPANY OVERVIEW



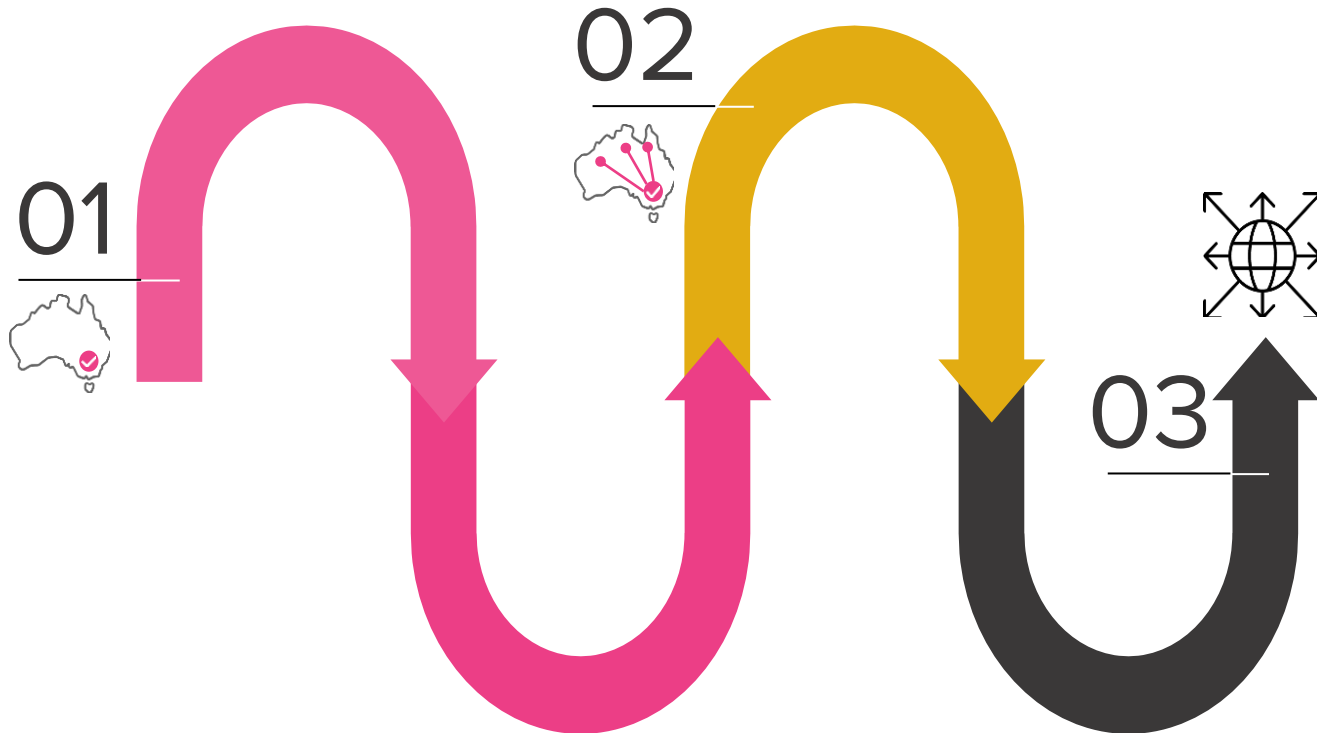
BREASTEST[®]
a blood test
that detects
breast cancer

- Founded in 2010, BCAL Diagnostics is focused on **transforming early detection and screening for breast cancer** for women worldwide with the introduction of its innovative blood test **BREASTEST[®]**
- **Over 5,000 prospective blood samples** have been collected by BCAL to drive test development and machine learning **AI algorithms**
- **Commercial launch in Australia in late 2024 and USA entry in 2025**
- **BREASTEST[®]** will be introduced initially as an adjunct to the current standard of care
- **Highly experienced leadership team** with a strong track record of success, and a network of Key Opinion Leaders (KOLs) to propel market entry

{ **BREASTEST[®]** is *game changing technology* for women in breast cancer screening. }

COMMERCIAL PATHWAY

A 3-year roadmap to saving lives underpinned by a reproducible lipidomic platform and a proprietary biobank of growing data.



01 Australian Launch

- Launch of BREASTEST® in Australia late 2024 & first revenues
- Initial focus on NSW & Victoria where we already have a strong footprint
- Accelerate education & awareness with Breast Surgeons, Breast Clinics, GP's, radiology and pathology providers, Breast care Nurses, Advocacy Groups, and Government agencies
- Develop and implement strategic partnerships to expedite mass market penetration

02 Scale nationally

- Nationwide market access initiatives to take BREASTEST® across Australia
- Define and initiate market entry strategy for US commercial launch
- Expand patient sample processing capacity of Sydney lab
- Grow the revenue with increased market access

03 Globalise

- Publish in scientific literature the clinical and utility performance of BREASTEST® to underpin other market launches
- Secure government funding for BREASTEST® in Australia
- Prepare for commercial launch in the US
- Expand intended use and develop products on BCAL's platform for other cancers
- Consolidate and continue to grow volume in Australia

A GLOBAL COMMERCIAL OPPORTUNITY

Breast cancer is the world's most prevalent cancer in women

WCRFI

13% of

women in the US will develop an invasive form of breast cancer in their lifetime

2024, BreastCancer.org

\$2.3B

2023 to

\$6.9B

2033

Persistence Market Research

On average

57 People

are or will be diagnosed with breast cancer everyday

BCNA

2.1 Million Mammograms in 2021 in AUS

BSA

310,720

cases of breast cancer are expected to be diagnosed in the US in 2024

2024, American Cancer Society

Women have a

1 in 7

chance of being diagnosed with breast cancer over their lifetime

NCBF

\$70M

USD 2024 to

\$108M

2029

Mordor intelligence

52.3 Million Mammograms in 2019 in the US

CDC

Breast Screening – Mammogram

Current Standard of Care

28%

(>20,000) of all new cancer cases in AU women will be breast cancer and **>3000 die from this disease each year**

BCN
A

40+

Guidelines limit access to routine screening to those over 40 years old

health.gov

2.1M

Mammograms occurred in Australia in 2023

AIH
W

42%

of eligible women in Australia **do not get screened:**

BreastScreen Australia

New data from the USA points to a

42% reduction

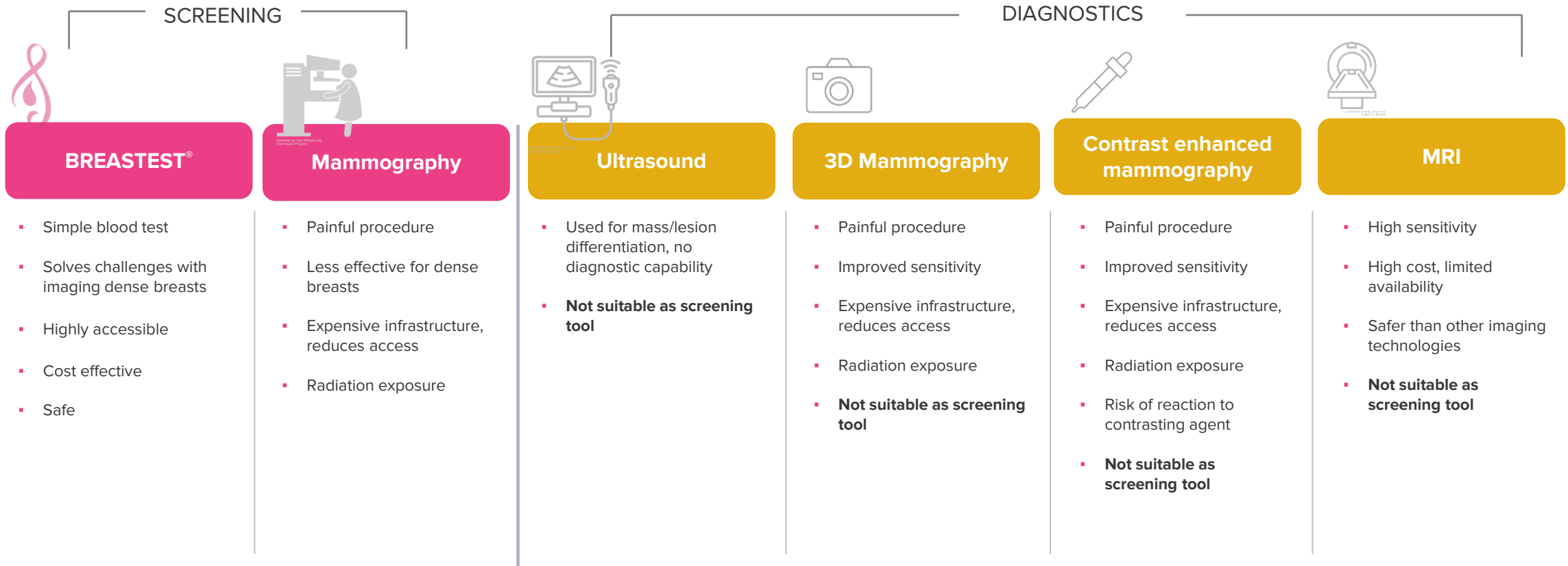
in mortality if annual screening introduced

<https://pubs.rsna.org/doi/10.1148/radiol.232658>

Current program limitations:

Breast density & old technology leading to high recall rates and false positives, patient experience, Mammogram only recommended every second year due to radiation dose/cost.

BREASTEST® WILL BE USED AS A SCREENING TOOL



A LIPID BLOOD TEST WITH AUTOMATED ANALYSIS

} A LIPIDOMIC PLATFORM THAT INCORPORATES AI MACHINE LEARNING AND LEVERAGES ROBUST SCIENTIFIC RESEARCH

~\$300

Proposed cost of test to the patient, following independent research and focus group

BREASTEST®

AT COLLECTION CENTRE



Blood collection



Whole Blood



Plasma
Erythrocytes

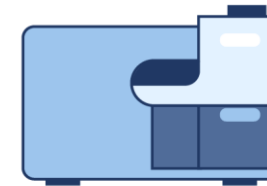
Pre-processing: sample spin, separate and freeze

TRANSIT



Sample preparation:
plasma lipid extraction

AT TESTING LABORATORY



Sample Analysis: Extracts analysed using Liquid Chromatography Mass Spectrometry (LCMS)



Data analysis for breast cancer lipid signatures (presence or absence)

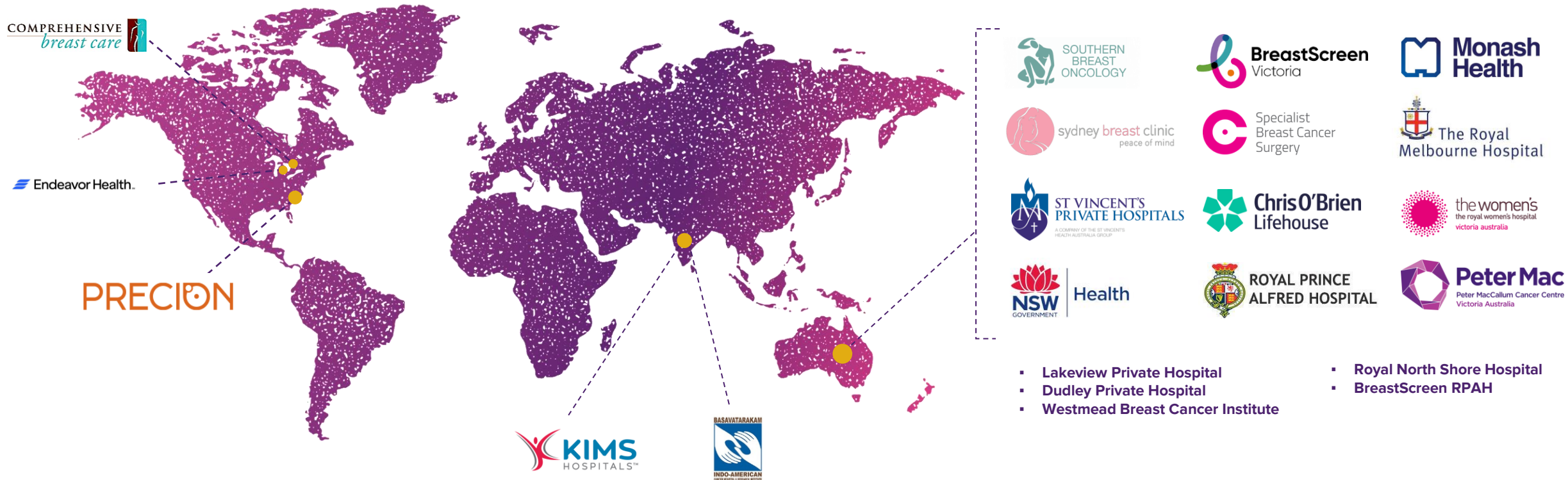
Logistics & processing scaling confirmed

COMMERCIAL LAUNCH ON TRACK FOR **LATE 2024**

} Commercial strategy to advance relationships with existing partners to launch BREASTEST® in specialised clinics with first revenues expected to be delivered immediately following launch.

	APR '24	MAY '24	JUN '24	JUL '24	AUG '24	SEP '24	OCT '24	NOV '24	DEC '24	JAN '25
BREASTEST® launch										
First Revenues										
BCAL research published in high profile journal										
BCAL presenting research at BCT, Leura International BCC, CoBrCa Edinburgh, SABCS USA.										
Australian clinical validation study										
Indian clinical study commences & completes										
BCAL signs agreements to collect patient samples with two healthcare providers in USA										
Execute commercial agreements with radiology providers										
Achieve NATA accreditation										
Formalise strategic partners to complete clinical validation study										
Receipt of BREASTEST® and BCAL Dx® trade marks										

BCAL IS WORKING WITH CLINICIANS FROM LEADING CENTRES AROUND THE GLOBE



A pilot study assessing the feasibility of using the BCAL test for early diagnosis of breast cancer in India

- Lakeview Private Hospital
- Dudley Private Hospital
- Westmead Breast Cancer Institute
- Royal North Shore Hospital
- BreastScreen RPAH

CLINIC ADVISORY BOARD

} Eminent and influential Breast Clinicians form a National Key Opinion Leader & Clinical Excellence Forum to enhance trust, provide advice and inform the BCAL program



Dr David Speakman



Prof Bruce Mann



Dr Corinne Ooi



A/Prof. James French



Prof. Elisabeth Elder



A/Prof. Cindy Mak



Dr Samriti Sood



A/Prof. Gillian Lamoury



Dr Sally Baron-Hay



Dr Mary Rickard OAM

BREASTEST™ HAS STRONG AND GROWING INTELLECTUAL PROPERTY

Title	IP covered	Jurisdiction	Status	Patent number	Priority date	Expected expiry date
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	AU (AU1)	Granted	AU Pat. No. 2011270968	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	AU (AU2)	Granted, Divisional filing	AU Pat. No. 2016213855	23 June 2010	22 June 2031
Methods related to cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	US (US2)	Pending, Divisional filing	US 17/305,824	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	CA (CA1)	Pending	CA 2,803,865	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	EP (EP1)	Granted	EP Pat. No. EP 2585833	23 June 2010	22 June 2031
Use of fatty acids in methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	EP (EP2)	Granted	EP Pat. No. 3206034	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	EP (EP4)	Pending	EP 21200018.6	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	HK (HK1)	Granted	HK Pat. No. 1180764	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	HK (HK2)	Pending	HK 42022052007.6	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	JP (JP1)	Granted	JP Patent No. 5944385	23 June 2010	22 June 2031
Methods for detecting cancer*	Use of plasma lipids as a diagnostic method to detect breast and lung cancer	JP (JP2)	Granted	JP Patent No. 6092302	23 June 2010	22 June 2031
Diagnostic signature	Use of plasma lipids as a diagnostic method to detect breast cancer in combination with machine learning algorithms	PCT stage	Pending	AU2023/050389	10 May 2022	10 May 2043
Diagnostic signature	Use of plasma lipids as a diagnostic method to detect breast cancer in combination with machine learning algorithms	AU Provisional	Provisional	2023903491	31 Octo 2023	N/A

*Licensed from University of Louisville Research Foundation Inc. European (EP) jurisdictions covered: DE, GB, FR, IT, NL, ES.

BOARD AND EXECUTIVES



Jayne Shaw
Executive Chair

Successful businesswoman, entrepreneur and co-founder. Previously co-founder and owner of the Sydney Breast Clinic.



Hon Ron Phillips AO
Non-executive Director

Health policy expert, previously Minister for Health in NSW Parliament and co-founder and owner of the Sydney Breast Clinic.



Mark Burrows AO
Independent
Non-executive director

An advocate for early diagnosis of breast cancer and other cancers. International banking expert and has held positions of Chairman and NED of major ASX listed corporations.



Jonathan Trollip
Independent
Non-executive Director

International businessman and lawyer. Many years of experience as NED of large ASX-listed companies.



Dr. John Hurrell PhD
Independent
Non-Executive Director and Consultant

More than 35 years' experience in life sciences & healthcare. Has developed & successfully commercialised multiple products & services as well as managing start up/early-stage companies.



Dr David Darling
Non-Executive Director

David Darling, former CEO of Pacific Edge, brings vast commercial expertise to BCAL with a genetics background and 30+ years experience.



Shane Ryan MBA
Chief Executive Officer

Shane Ryan, former Global SVP of Strategy & Innovation at GenesisCare, with 20+ years in oncology, specializes in breast cancer, excelling in patient care, research, and innovative service models.



Dr Amani Batarseh PhD
Chief Scientific Officer

PhD from Georgetown University, Washington, DC Completed post-doctoral studies at Harvard, McGill and Wollongong Universities. Expert in molecular biology lipidomics and mass spectrometry.



Guy Robertson
Chief Financial Officer &
Company Secretary

A Finance Director/Chief Financial Officer for a number of companies within the Jardine Matheson Group over a period of 16 years. Provides CFO and company secretary consulting services to many large corporations and SMEs.



Alison Cook (Mew), MSc
Quality and Regulatory
Advisor

Management and leadership experience of more than 30 years across the biopharmaceutical, diagnostic and health service sectors. Spent 13 years in senior executive roles at CSL Limited. Consulted widely across the life sciences industry.



Kathy Koskiris BSc. MBA.
Director, Clinical Laboratory
Services

More than 20 years' experience in building and managing clinical laboratories under TGA and US CLIA regulations. Managed CLIA certification for multiple new products, CLEP certification and NATA Accreditation with ISO15189 & NPAAC standards.



Dr Simon Preston
Director Clinical Research

15 years of Research and Development experience across academic and industry roles. Extensive clinical and preclinical experience in both pharmaceutical and diagnostics.



Thank you

Jayne Shaw
Executive Chair
jshaw@bcaldiagnostics.com

Shane Ryan
Chief Executive Officer
sryan@bcaldiagnostics.com

BCAL Diagnostics Limited
ABN 51 142 051 223
Suite 506, Lvl 5,
50 Clarence Street
Sydney NSW 2000

www.bcaldiagnostics.com