



**BCAL DIAGNOSTICS LIMITED**

**ASX: BDX**

# **CORPORATE PRESENTATION**

**6 MARCH 2024**

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# BCAL BREASTEST™

DRIVING A NEW PARADIGM IN BREAST CANCER  
DIAGNOSTICS

**Founded in 2010, BCAL Diagnostics is an Australian diagnostic company focused on revolutionising early detection and screening for breast cancer for women worldwide**

# H1 HIGHLIGHTS



**1**

**Scientific progress**

Breakthrough results from clinical study with Precion

Completion of pre-analytical blood processing optimisation studies

**Laboratory & Processing**

NATA accreditation application well underway

Launch of SENSIBLE study confirming accuracy and consistency per final protocol



**2**



**3**

**Corporate developments**

Formation of Clinical Advisory Board

Key management and clinical appointments to support commercialisation

**Partnerships**

Sample collection partnerships with KIMS Institute and Indo-American Hospital, India

Further partnerships with advocacy groups



**4**

# SIGNIFICANT SCIENTIFIC PROGRESS

## PRECISION STUDY

The analysis undertaken achieved an impressive sensitivity of 90% and a specificity of 85.5% in internal validation studies involving 656 samples.

The samples were collected and processed from Australian breast cancer patients and healthy control subjects according to BCAL protocol.

Demonstrates robustness of the BCAL breast cancer plasma lipid signature and the transferability of the test between laboratories and instrument types.

## BLOOD PROCESSING OPTIMISATION

Completed all studies to determine the tolerable limits and instructions for collection, transportation, processing, and storage of patients' samples before pathology testing. This ensures results obtained are **accurate and consistent**.

Collected over 2,500 samples from biopsy-confirmed breast cancer patients and healthy controls from Europe, Australia, and the USA, with 9% of Australian samples positive for breast cancer

# FINAL STAGE AHEAD OF COMMERCIAL LAUNCH

## LAB ACCREDITATION

National Association of Testing Authorities (NATA) under the ISO 15189 requirements and National Pathology Accreditation Advisory Council (NPAAC) certifications are required

Completion of implementation of the Quality Management System required

Completed NATA advisory visit in December 2023



## SENSIBLE STUDY

BCAL has initiated a further internally-managed clinical study, the SENSIBLE study, using samples from Australian patients collected and processed using the commercial protocol

This study will continue into Q3 FY24 but an early analysis of the data being collected indicates continued concordance with the data collected in the US study previously reported, and earlier, locally-acquired data.

# CORPORATE DEVELOPMENTS

## Strategic changes to expedite commercialisation pathway

- Formation of Clinical Advisory Board to assist the company in clinical utility decisions
  - Made up of leading breast cancer clinicians and researchers
- Simon Preston appointed as Director of Clinical Research
  - Bringing 15 years research experiences within the academic and diagnostic industries
- CEO John Hurrell transitions to position of Consultant and Executive Director
- Shane Ryan transitions to CEO effective 1<sup>st</sup> April 2024
  - Originally appointed in September 2023 as COO

# BREASTEST™

**A blood test that detects breast cancer that will be ready for use in Australian women in late 2024**

- **14 years of clinical development** with research originating in Sydney in 2010
- **Developed in clinical studies using cutting edge lipidomics in more than 2500 patient samples**
- **Launch in Australia in 2024 and planning for USA market entry in 2025**
- **Initial intended use alongside current breast cancer diagnostic tools** including mammography
- **BCAL is led by a highly experienced commercial and scientific management team** ready for commercial launch
- **BREASTEST™ will be processed in BCAL's laboratory in Sydney**

*For women who are currently participating in screening programs and available to those who cannot or choose not to.*

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*We are passionate about changing the way we think about detecting breast cancer, diagnosing it as early as possible, and ultimately improving outcomes for breast cancer patients.*

# INVESTMENT HIGHLIGHTS

## A BLOOD TEST TO DETECT BREAST CANCER

- 1. Revenue generation** following Australian market launch in late 2024
- 2. A complementary solution to traditional diagnostic technologies** overcoming many of the existing challenges of the current screening program
- 3. Set to transform the global landscape of breast cancer diagnosis, monitoring, and surveillance** with proprietary lipid detection technology that can be also applied to other cancers
- 4. Set to drive improved participation rates in breast cancer screening programs** with intended focus on those who currently do not or cannot participate
- 5. Leverages AI-driven technology in BCAL-owned laboratory and operated Biobank**, distinguishing from competitors by collecting its own samples with strong clinical protocols and governance in place
- 6. 2.1 million mammograms** took place in 2023 although **1.5 million** people who were eligible did not get screened *(BreastScreen Australia)*

# COMMERCIAL PATHWAY

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

## 1 AUSTRALIAN LAUNCH '24

- Launch of BREASTEST™ in Australia late 2024
- First revenues immediately following launch
- Building relationships with Key Opinion Leaders (KOLs) and breast surgeons to penetrate existing screening programs
- Develop and implement strategic partnerships to expedite mass market penetration
- Finalise laboratory accreditation for commercial samples

2

3

## GLOBALISE

- Publish in scientific literature the clinical and utility performance of BREASTEST to underpin other market launches
- Secure government funding or BREASTEST™ in Australia
- Commercially launch in the US
- BREASTEST™ incorporated into new standard of care of screening and diagnosis
- Used for high-risk patients, remission treatment and monitoring
- Develop products on BCAL's platform for other cancers

## SCALE NATIONALLY

- Nationwide patient access to BREASTEST™ across Australia
- Define and initiate market entry strategy for US commercial launch
- Expand patient sample processing capacity of Sydney lab by scaling laboratory
- Expand the lipidomic platform
- Expand Lipidomic platform into other cancer streams
- Grow the revenue with increased market access

# A MAJOR 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, BreastImaging.org

**310,720** cases of breast cancer are expected to be diagnosed in the US in 2024

2024, American Cancer Society

**52.3 Million Mammograms in 2019**

CDC

On average **57 People** are or will be diagnosed with breast cancer everyday

**2.1 Million Mammograms in 2021**

BSA

There are **100,000** people in Australia today who have had a breast cancer diagnosis in the last 5 years

BCNA

BCNA

Women have a **1 in 7** chance Risk of being diagnosed with breast cancer over their lifetime

NCBF

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# EARLY DIAGNOSIS SAVES LIVES AND COSTS TO THE HEALTHCARE SYSTEM

## BREAST CANCER STAGES



**STAGE 0**

**100%  
SURVIVAL  
RATE**

**\$16,390**



**STAGE 1**

**98%  
SURVIVAL  
RATE**

**\$44,367**



**STAGE 2**

**93%  
SURVIVAL  
RATE**

**\$86,383**



**STAGE 3**

**72%  
SURVIVAL  
RATE**

**\$110,364**



**STAGE 4**

**28%  
SURVIVAL  
RATE**

**\$418,549**

**Cost of healthcare  
per patient (CA\$)\***

*BCAL is  
focused on  
improving the  
outcomes for  
women with  
breast cancer*

## LIMITATIONS OF MAMMOGRAPHY:

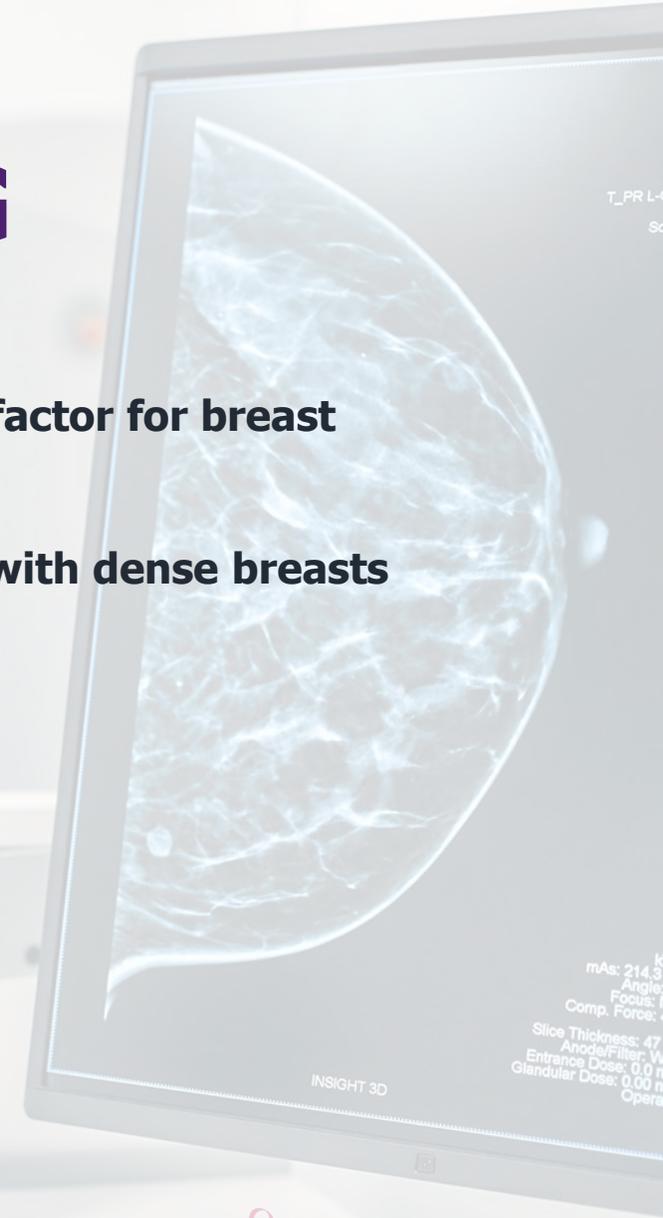
- Guidelines limit access to those over 40yo
- Most effective above 50yo due to lower breast density and fatty tissue
- Limited remote access
- Prone to self-exclusion (painful, uncomfortable, cultural reasons)
- Significantly less effective for patients with higher risk such as younger people and those with higher breast density

# CURRENT BREAST CANCER SCREENING

**Breast density is the least addressed common risk factor for breast cancer accounting for up to 50% of cases.**

**There's an unmet need to detect cancer in women with dense breasts**

- 40–50% of US women have dense breast tissue *(CDC)*
- Incidence is 4-6x more likely in women with dense breasts *(CDC)*
- BCAL has a two-pillared market entry strategy that focuses on the initial launch of BREASTEST™ as an adjunct to existing screening methods



# 2.1 MILLION MAMMOGRAM SCREENINGS

occurred in Australia in 2023, well short of the expected 4million

**42%**

of eligible  
women do not  
get screened

*(BreastScreen Australia)*

**44%**

women think  
waiting two  
years for a  
mammogram is  
too long

*(BMC Cancer)*

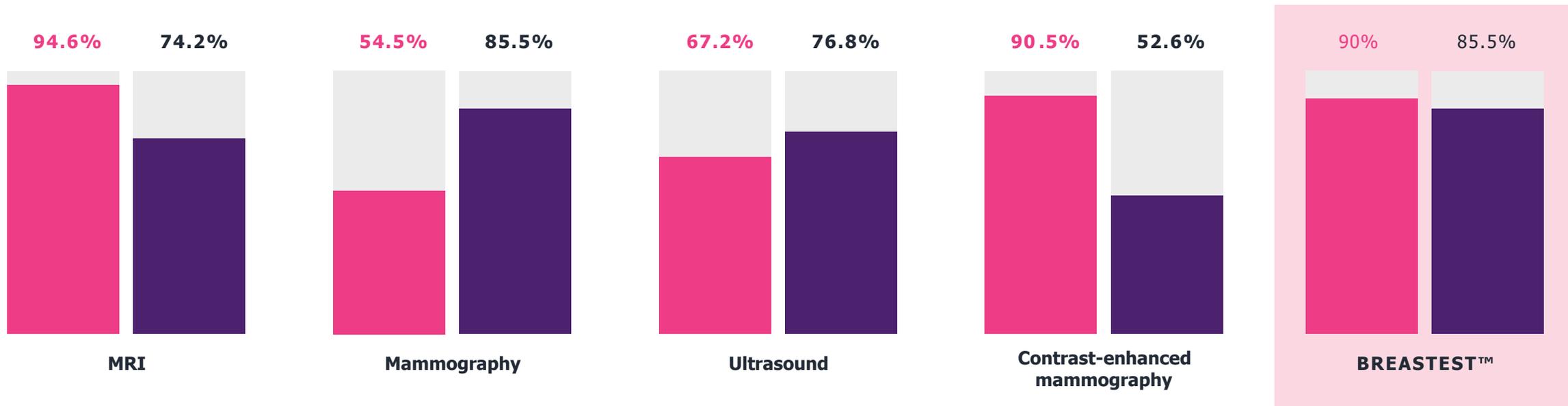
**28%**

Of all new  
cancer cases in  
women will be  
breast cancer

*(BCNA)*

# BREASTEST™ INTEGRATED EXISTING STANDARDS OF CARE

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A cancer detection test requires a balance of sensitivity (ability to detect true positive samples) and specificity (ability to detect true negative samples).

- SENSITIVITY
- SPECIFICITY

Internal validation of BREASTEST™ shows strong potential performance with a balance between sensitivity and specificity.

# PATH TO MARKET

Strategy defined to provide a sequenced path to market

## Adjunct test

Adjunct test to traditional mammogram screening

## Monitoring

Monitor breast cancer patients through the disease lifecycle

## Surveillance

Monitor women who carry gene mutations or considered to be high risk

## Diagnostic

Comprehensive breast cancer screening for all patients

# DETECTING LIPID SIGNATURES FROM BREAST CANCERS



Lipids are fats and a source of energy for cell growth.



Deregulation of lipid metabolism is a very early step in a normal cell becoming a cancerous cell.



Deregulated lipids can spill over into the blood's plasma which is indicative of cancer growth.



**BREASTEST™** can detect levels of lipids in the blood plasma and subsequently diagnose cancer earlier than conventional methods.

*BCAL has developed a lipidomic platform for breast and other cancers*

# LIPID BLOOD TEST WITH AUTOMATED ANALYSIS

~\$300  
Proposed cost of test to the patient, following independent research and focus group

During Phase 1 of the commercial launch, BCAL will manage the pathology logistics to ensure quality control and ongoing sample storage to further develop its AI data analytics platform.

Ongoing consideration of pathology partnership is to support the financial burden of pathology from mass testing.

## BREASTEST™

### AT COLLECTION CENTRE



Blood collection



Whole Blood

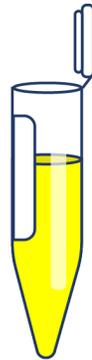


Plasma

Erythrocytes

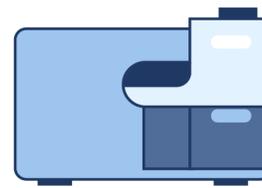
Pre-processing: sample spin, separate and freeze

### 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)

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# BCAL IS WORKING WITH CLINICIANS FROM LEADING CENTERS AROUND THE GLOBE



Comprehensive Breast Centre  
Endeavor Health

PRECISION

- US lab partner
- 1 site, Prospective
- 2-3 sites, Prospective
- 4+ sites, Prospective



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



sydney breast clinic  
peace of mind



ST VINCENT'S PRIVATE HOSPITALS  
A COMPANY OF THE ST VINCENT'S HEALTH AUSTRALIA GROUP



Health  
Northern Sydney Local Health District



Chris O'Brien Lifehouse



ROYAL PRINCE ALFRED HOSPITAL

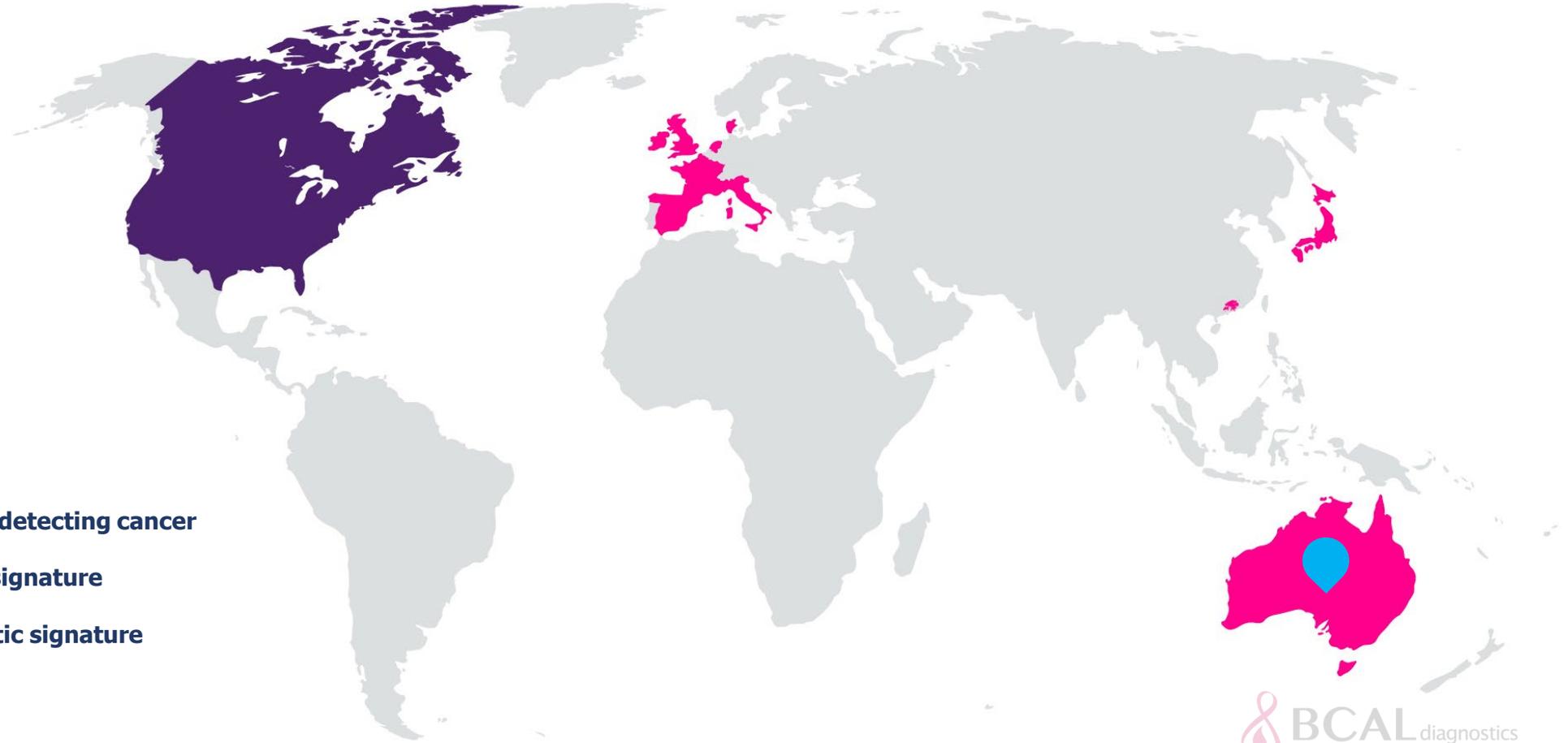


- Lakeview Private Hospital
- Dudley Private Hospital
- The Royal Melbourne Hospital
- The Royal Women's Hospital
- Monash Health
- Peter MacCallum Cancer Centre
- Specialist Breast Cancer Surgery
- Westmead Breast Cancer Institute

Personalized

# INTERNATIONAL INTELLECTUAL PROPERTY (IP) PROTECTION

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- **Granted as a method for detecting cancer**
- **Pending as a diagnostic signature**
- **In Progress as a diagnostic signature**

# Clinical 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**

Former CMO at Peter MacCallum Cancer Centre. A specialist breast and melanoma surgeon. Recipient of the Tom Reeve Award for outstanding contribution to cancer care, and Clinical Director at Breast Screen Victoria.



**Prof Bruce  
Mann**

Professor of Surgery, The University of Melbourne. Director of Breast Tumour Stream the Victorian Comprehensive Cancer Centre. Director of Research, Breast Cancer Trials.



**Dr Corinne Ooi**

Head of Breast Service at Monash Health, VMO at Monash BreastScreen, and a Foundation Member of BreastSurgANZ, a specialist society for surgeons treating breast cancer. Member of the Australasian Society of Breast Diseases, ANZ Breast Cancer Trials Group, and General Surgeons Australia.



**A/Prof. James  
French**

Experienced Oncoplastic Surgeon who operates in both public and private settings. He is the Head of Breast Surgery at the Westmead Breast Cancer Institute and chair of two MDM meetings.

James is also part of the team leading the development of oncoplastic breast surgery.



**Prof. Elisabeth  
Elder**

Specialist Breast Surgeon at the Westmead Breast Cancer Institute and privately through Specialist Services at Lakeview Private Hospital. Elisabeth is a surgeon at the forefront of the developing field of oncoplastic breast surgery and former President of the Australian Society for Breast Disease.

# Clinical Advisory Board



**A/Prof. Cindy Mak**

Sydney qualified and trained Breast Surgeon, and chair of the Oncoplastic Sub-Committee of BreastSurgANZ. Director of Breast Services at Chris O'Brien Lifehouse (Camperdown).

She also operates at the Mater Hospital (North Sydney) and Royal Prince Alfred Hospital.



**Dr Samriti Sood**

Specialist Oncoplastic Breast Surgeon who offers expertise in the management of women with all breast-related conditions.

Operates at The Mater, Royal North Shore and Northern Beaches.



**A/Prof. Gillian Lamoury**

Radiation Oncologist with a sub-specialty in breast cancer.

Based at The Mater and Royal North Shore.



**Dr Sally Baron-Hay**

Medical Oncologist with over 20 years of clinical experience and senior lecturer at the University of Sydney.

She has clinical appointments at Royal North Shore Hospital in Sydney, North Shore Private Hospital, The Mater Hospital and Genesis Care.



**Dr Mary Richard OAM**

Leading Sydney based Radiologist with sub-specialty in Breast cancer.

Involved in consulting with numerous breast screening and diagnostic training programs across South East Asia, in particular Singapore, Indonesia, Malaysia, Thailand, Japan and Mongolia.

# COMMERCIAL LAUNCH ON TRACK FOR LATE 2024

Commercial strategy to advance relationships with existing partners to launch BREASTEST™ in specialised clinics with first revenues 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
<b>BREASTEST™ launch</b>										
First Revenues										
Community awareness initiatives including GPs, advocacy groups and government										
BCAL research published in high profile journal										
BCAL presenting research at BCT annual scientific meeting										
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										
North Ryde laboratory receives NATA accreditation										
Continued signing of strategic partners to complete clinical validation study										

# BOARD OF DIRECTORS



**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.



**Jonathan Trollip**  
**INDEPENDENT NON-EXECUTIVE DIRECTOR**

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



**David Darling**  
**INDEPENDENT NON-EXECUTIVE DIRECTOR**

Over 30 years of executive leadership, growing and commercialising biotechnology and life sciences companies



**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.

## EXECUTIVE TEAM - AUSTRALIA



**Dr. John Hurrell, PhD**  
**CHIEF EXECUTIVE OFFICER**

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



**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 several 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.



**Simon Preston, PhD**  
**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.



**Shane Ryan, MBA**  
**CHIEF OPERATING OFFICER**

Former Global SVP of Strategy & Innovation - Patient Access at GenesisCare, boasting 20+ years in global oncology specialising in breast cancer. His contributions include precision medicine tests and clinical trials for high-risk breast cancer. Previously, he held executive roles at Peter MacCallum Cancer Centre for a decade.



**Kathy Koskiris BSc. MBA.**  
**DIRECTOR, CLINICAL LABORATORY SERVICES**

More than 20 years of 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.

# Thank you

**Jayne Shaw**  
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**John Hurrell**  
Chief Executive Officer  
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