



BCAL DIAGNOSTICS LIMITED

ASX: BDX

CORPORATE PRESENTATION

6 MARCH 2024

Jayne Shaw | John Hurrell | Shane Ryan

IMPORTANT NOTICE AND DISCLAIMER

This presentation (Presentation) has been prepared by BCAL Diagnostics Ltd ABN 51 142 051 223 (BCAL or the Company).

The information in this Presentation is of a general background nature, is in summary form and does not purport to be complete. The information in this Presentation is subject to change without notice and, subject only to any legal obligation to do so, BCAL does not have any obligation to correct or update the contents of this Presentation.

The Presentation contains certain "forward-looking statements". The words "forecast", "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this Presentation are based on assumptions and contingencies which are subject to change without notice and involve known and unknown risks and certainties and other factors which are beyond the control of BCAL, and its directors and management, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct. This includes statements about market and industry trends, which are based on interpretations of current market conditions.

Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. Actual results, performance or achievements may differ materially from those expressed or implied in such statements and any projections and assumptions on which these statements are based. Recipients are cautioned not to place undue reliance on forward-looking statements. Refer to the risk factors section of this Presentation for some of the key known risks. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this Presentation.

The forward-looking statements are based on information available to BCAL as at the date of this Presentation. Circumstances may change and the contents of this Presentation may become outdated as a result. Except as required by law or regulation, none of BCAL, its representatives or advisers undertakes any obligation to provide any additional or updated information whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements.

No party other than BCAL has authorised or caused the issue, lodgement, submission, dispatch or provision at the end of this Presentation, or takes any responsibility for, or makes or purports to make any statements, representations or undertakings in this Presentation. To the maximum extent permitted by law, BCAL (including its subsidiaries, related bodies corporate, shareholders, affiliates, advisers and agents):

- disclaims all responsibility and liability (including, without limitation, any liability arising from fault, negligence or negligent misstatement) for any loss arising from this Presentation or reliance on anything contained in or omitted from it or otherwise arising in connection with this Presentation;
- disclaims any obligations or undertaking to release any updates or revision to the information in this Presentation to reflect any change in expectations or assumptions; and
- does not make any representation or warranty, express or implied, as to the accuracy, reliability or completeness of the information in this Presentation or the likelihood of fulfilment of any forward-looking statement or any event or results expressed or implied in any forward-looking statement.

Not An Offer

This Presentation is not a prospectus, product disclosure document or other offering document under Australian law (and will not be lodged with ASIC) or any other law. This Presentation is for information purposes only and should not be considered as, an offer, solicitation, inducement, recommendation or an invitation to acquire securities in BCAL or any other financial products, and neither this document nor any of its contents will form the basis of any contract or commitment.

This Presentation may not be distributed to any person in any country outside Australia except to the extent permitted under applicable laws. The release, publication or distribution of this Presentation (including an electronic copy) outside Australia may be restricted by law. If you come into possession of this Presentation, you should observe such restrictions and should seek your own advice on such restrictions. Any non-compliance with these restrictions may contravene applicable securities laws.

Not Financial Product Advice



This Presentation is not financial product, investment advice or a recommendation to acquire BCAL securities and has been prepared without taking into account the objectives, financial situation or needs of individuals. Each recipient of this Presentation should make its own enquiries and investigations regarding all information in this Presentation including, but not limited to, the assumptions, uncertainty and contingencies which may affect future operations of BCAL and the impact that different future outcomes may have on BCAL. Before making an investment decision prospective investors should consider the appropriateness of the information having regard to their own objectives, financial situation and needs, and seek legal, taxation and financial advice appropriate to their jurisdiction and circumstances. BCAL is not licensed to provide financial product advice in respect of its securities or any other financial products.

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 1st 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.

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

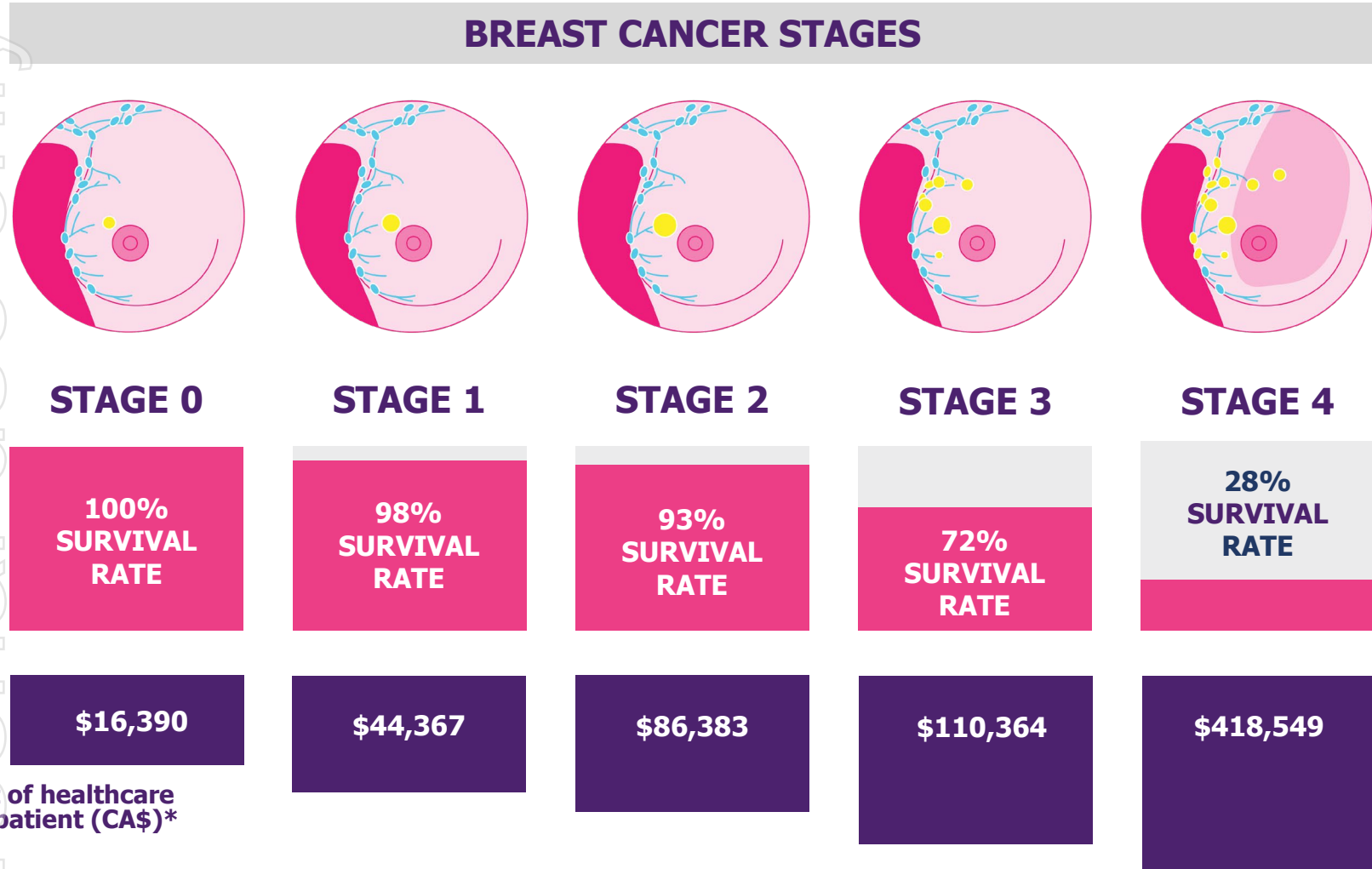
BCNA

BCNA

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

NCBF

EARLY DIAGNOSIS SAVES LIVES AND COSTS TO THE HEALTHCARE SYSTEM



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

*Article: Capturing the True Cost of Breast Cancer Treatment: Molecular Subtype and Stage-Specific per-Case Activity –Based Costing, 2023

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

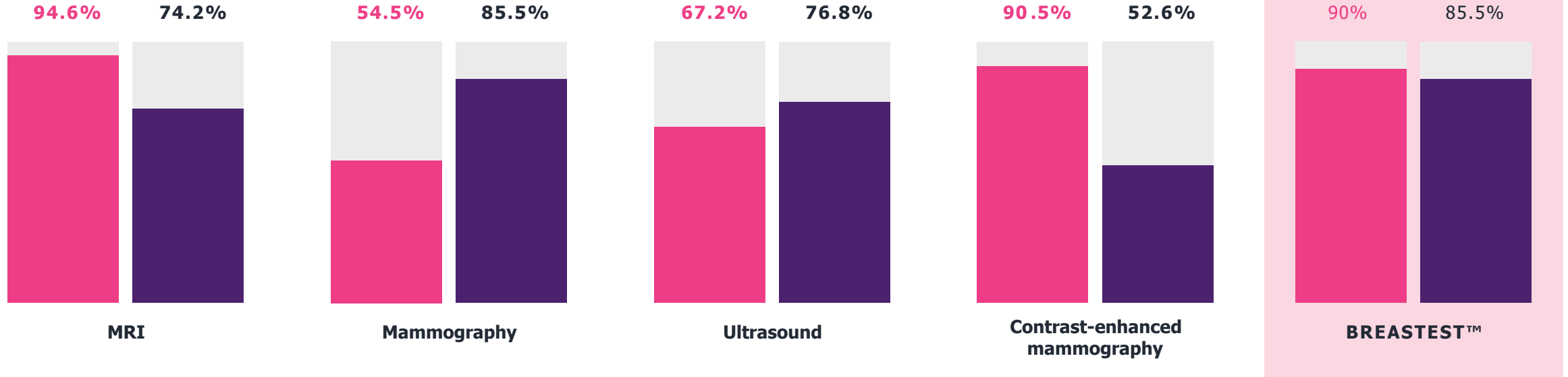
(BMC Cancer)

28%

Of all new
cancer cases in
women will be
breast cancer

(BCNA)

BREASTEST™ INTEGRATED EXISTING STANDARDS OF CARE



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

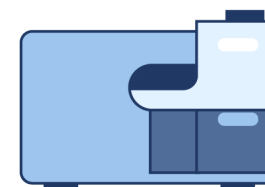
Pre-processing: sample spin, separate and freeze

TRANSIT

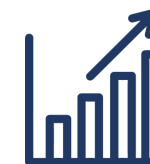


Sample preparation:
plasma lipid extraction

AT TESTING LABORATORY

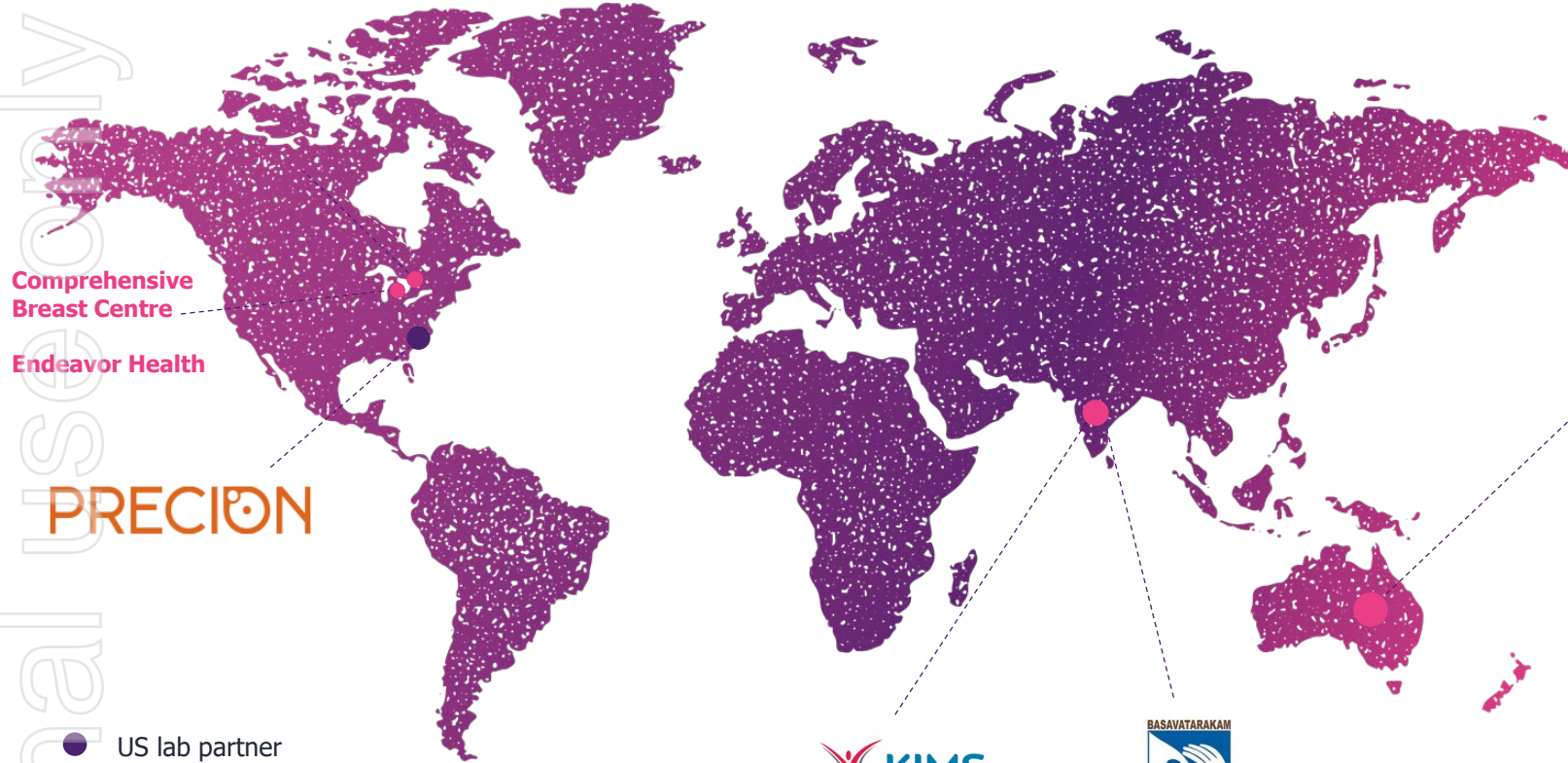


Sample Analysis: Extracts
analysed using Liquid
Chromatography Mass
Spectrometry (LCMS)



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

BCAL IS WORKING WITH CLINICIANS FROM LEADING CENTERS AROUND THE GLOBE



Comprehensive Breast Centre

Endeavor Health

PRECION

KIMS
HOSPITALS™

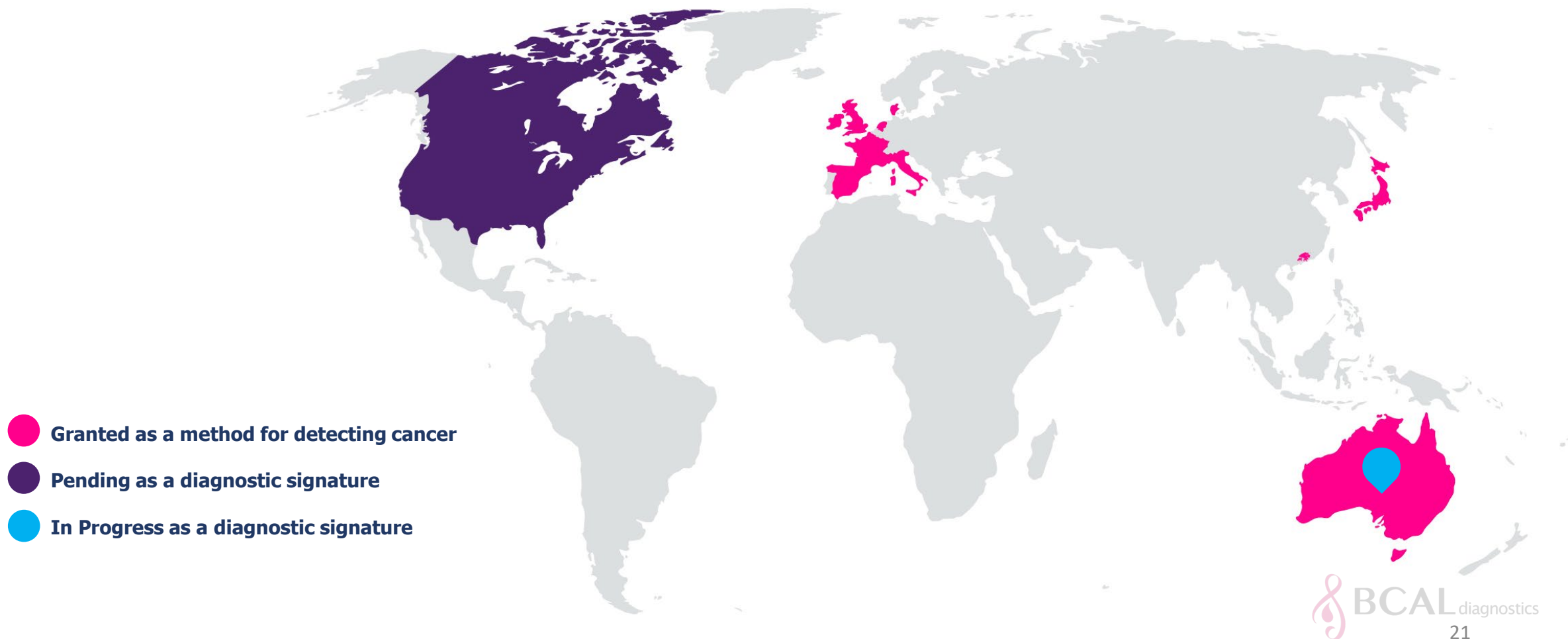
BASAVATARAKAM
INDO-AMERICAN
CANCER HOSPITAL & RESEARCH INSTITUTE

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

INTERNATIONAL INTELLECTUAL PROPERTY (IP) PROTECTION



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
BREASTEST™ launch										
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
Executive Chair
jshaw@bcaldiagnostics.com

John Hurrell
Chief Executive Officer
jhurrell@bcaldiagnostics.com

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

www.bcaldiagnostics.com

