



11 July 2024

ASX Announcement

**BCAL Diagnostics Corporate Presentation**

Attached please find a Corporate Presentation to given by Jayne Shaw, Executive Chair of BCAL Diagnostics, at the 18th Bioshares Biotech Summit at the Esplanade Hotel in Fremantle, Western Australia on the 13 July 2024.

This announcement and presentation approved for lodgement with the ASX by the Board.

Guy Robertson  
Company Secretary

ersonal use only



DRIVING A NEW PARADIGM IN BREAST CANCER DIAGNOSTICS



Bioshares Biotech Summit

Jayne Shaw | JULY 2024

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# COMPANY METRICS



## ASX Code

**BDX**

Share Price  
08 July 2024

**\$0.145**

Shares on Issue

**314M**

## Unlisted Options

**4.5M**

Cash  
30 June 2024<sup>1</sup>

**\$6.5M**

## Top 20 Shareholders

**52%**

Pre 15 July 2024 General Meeting regarding Tranche 2 of capital raise. If all of Tranche 2 is approved, cash increases by \$4.3m and shares on issue increase by 43M.

# A LIPID BLOOD TEST WITH AUTOMATED ANALYSIS

~\$300

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

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

BREASTEST®

## AT COLLECTION CENTRE



Blood collection



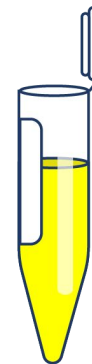
Whole Blood



Plasma  
Erythrocytes

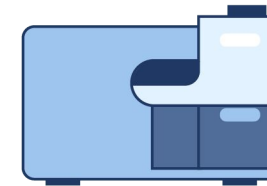
Pre-processing: sample spin, separate and freeze

## TRANSIT



Sample preparation:  
plasma lipid extraction

## AT TESTING LABORATORY



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

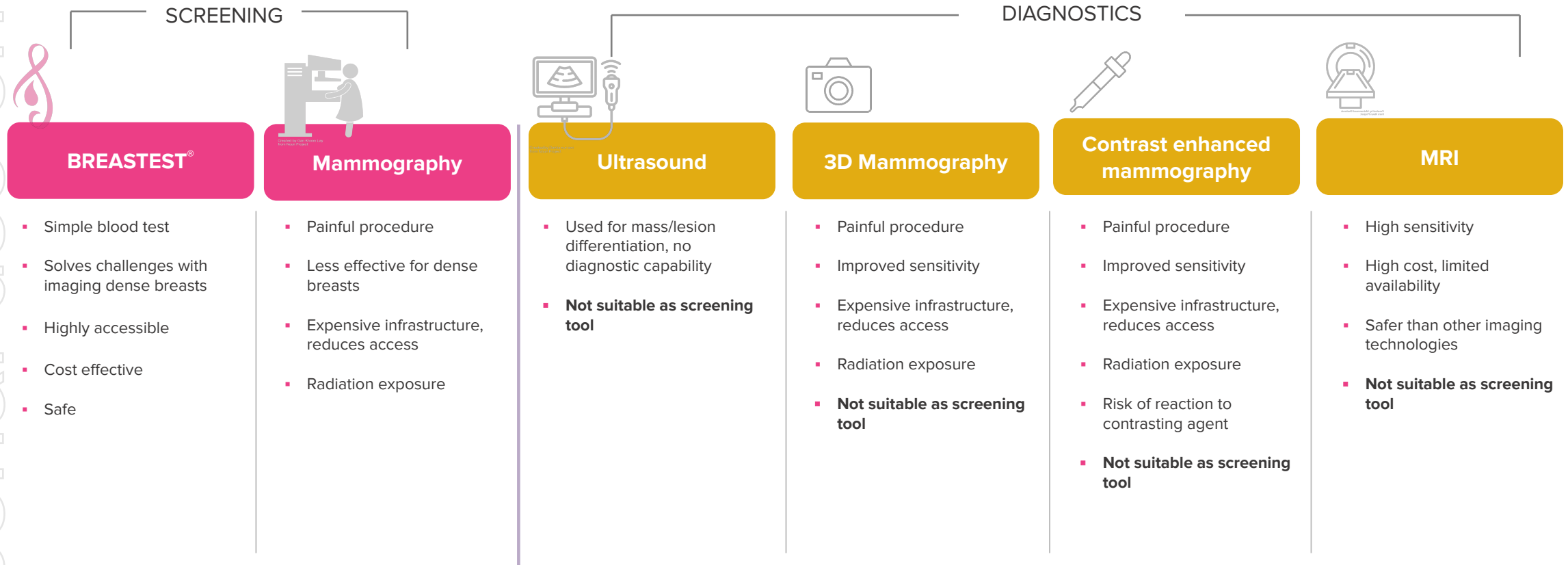


Data analysis for breast cancer lipid signatures (presence or absence)

Logistics & processing scaling confirmed



# BREASTEST® WILL BE USED AS A SCREENING TOOL





# REGULATORY PATHWAY TO COMMERCIALISATION

SEPTEMBER 2024

DECEMBER 2024

NATA is responsible for accrediting  
laboratories that develop/manufacture In  
Vitro Diagnostics (IVDs) in-house

Establish:  
“Medical Testing Laboratory”  
ISO 15189  
National Pathology Accreditation Advisory  
Council (NPAAC)  
Per Therapeutic Goods (Medical Device)  
Regulations 2002

Laboratory  
NATA  
accreditation  
(Sept 24)

Ongoing generation of analytical data to validate BREASTEST®

SENSIBLE Studies

CLINICAL VALIDATION STUDY  
Multi-center observational study

**BREASTEST®**  
launch

Commercialise  
test and supply  
in-house



# AUSTRALIAN LAUNCH

Launch of BREASTEST® in Australia late 2024 & first revenues

## NSW & VIC

**Q3 CY 2024**

Leverage existing sample collection sites prioritising those who can convert to commercial partners e.g. Sydney Breast Clinic

Targeting breast cancer Multidisciplinary Teams (MDT) and Primary Care Providers (GP's)

## OTHER AUS STATES

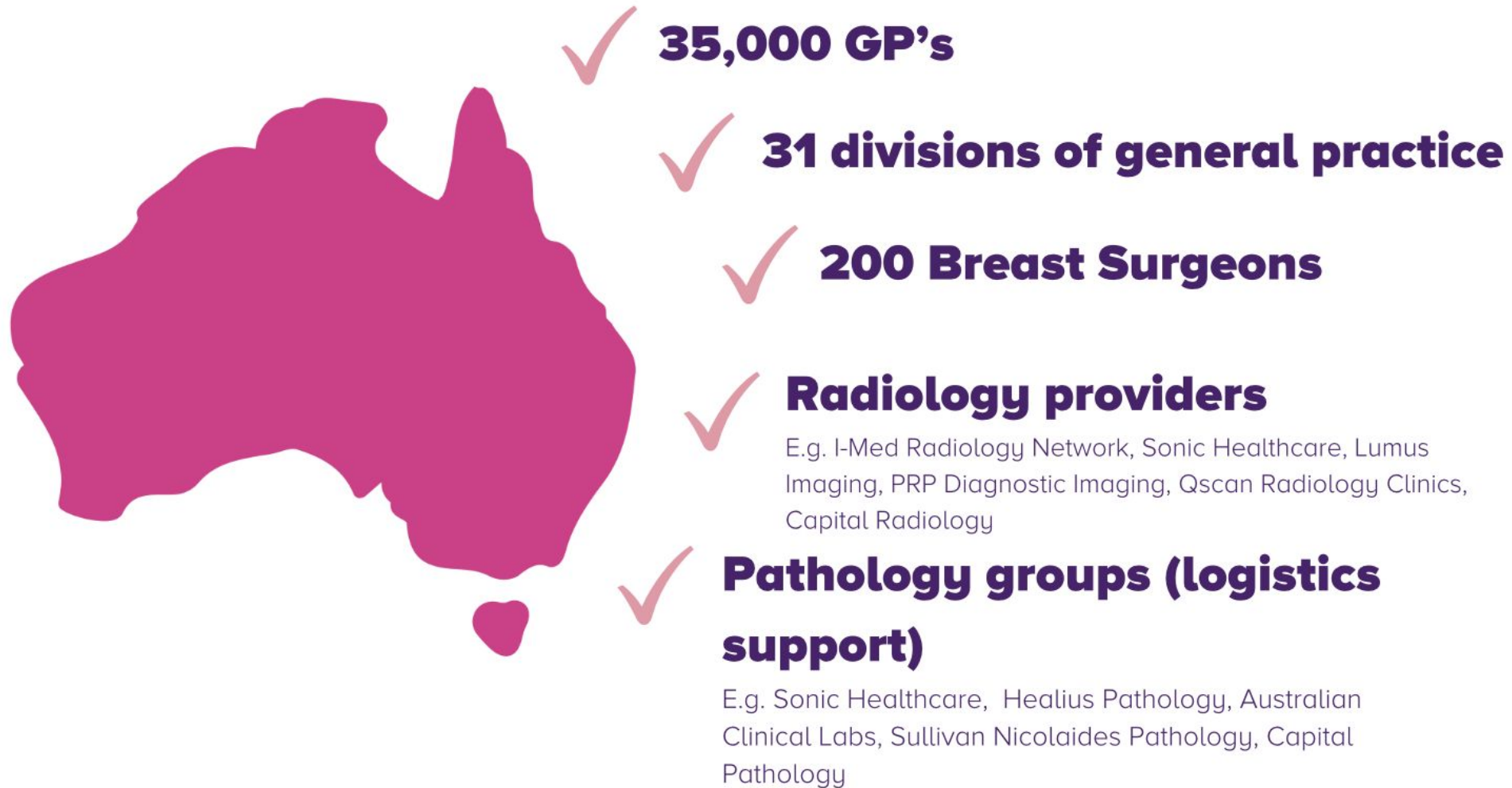
**Q3 CY 2024**

Focus on raising awareness

**Q3 CY2024 APPROACH : NSW & VIC focus + raising awareness in other states**

- Who: KOLs and Market Access Team
- Matrix style: Including 1:1 meetings, conference presentations, dinners, educational webinars
- Accelerate education & awareness: Breast surgeons, Breast Clinics, GP's radiology and pathology providers, breast care nurses, advocacy groups and govt agencies
- Develop and implement strategic partnerships: Expediate mass market penetration

# AUSTRALIAN DISTRIBUTION LANDSCAPE



# COMPREHENSIVE EDUCATION PROGRAM



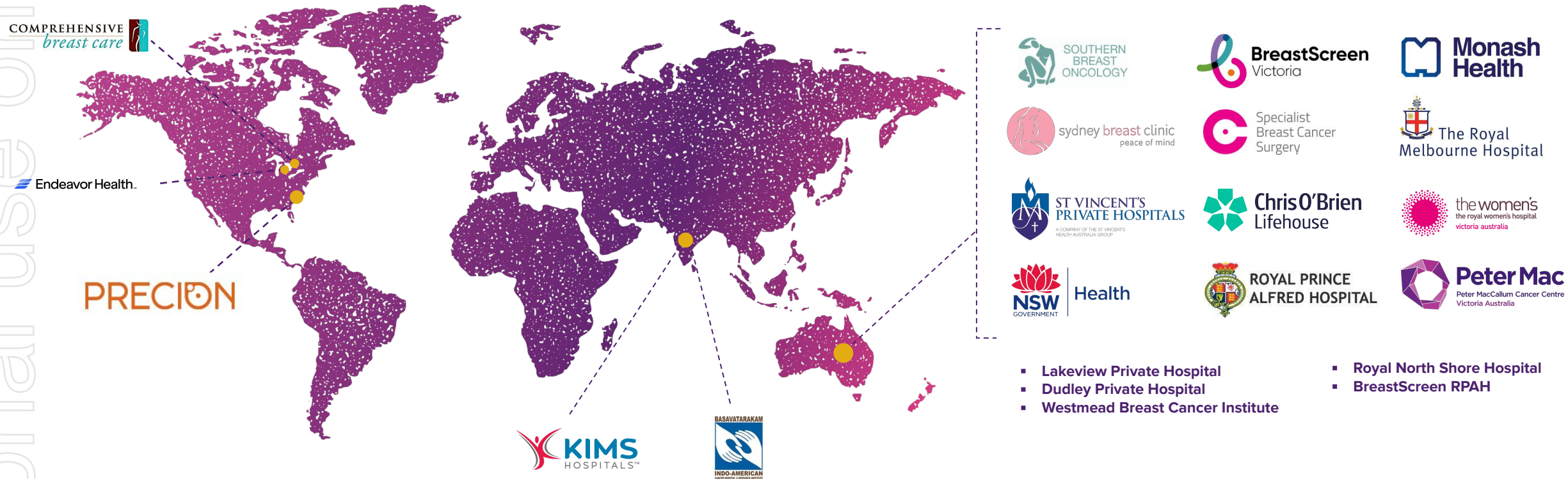
Establish BREASTEST® as effective, best-in-class screening technology for breast cancer

Personal Use Only

Community	Advocacy	Referral network	GP's	Breast Surgeons	Lab diagnostics network /Pathology groups/Radiology providers
Social media campaigns and influencers Community health seminars Collaborations with women's health organisations	Continued support and collaboration with advocacy groups such as Breast Cancer Network Australia, So Brave, Sydney Breast Cancer Foundation and Pink Hope.	Build a robust referral network by collaborating with top hospitals, clinics, and health centres. Use CRM tools to manage and streamline referrals. Establish a feedback loop with referring physicians to ensure seamless patient care.	Professional seminars and workshops Continuing Medical Education (CME) credits Detailed informational brochures and clinical evidence	Direct presentations at surgical conferences Peer-reviewed journal publications Collaborative case studies and clinical trial results	Patient management software programs for GP's & Specialists such as Medical Director, HCN, Sonic Software, Best Practice, Medtech Evolution



# 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

# FOCUS MARKET SEGMENTS

## FOUR INITIAL KEY TARGET SEGMENTS

1

### Adjunct to current standard of care

#### Phase 1 of launch;

- Working with existing screening partners in private health sectors
- Generate first revenues while continuing to build the databank

2

### Dense breast tissue

~40% if women have dense of extremely dense breast tissue;

- Younger women tend to have more dense breast tissue.

3

### Those who are not screened

1.5 million people who;

- Self exclude to due a personal preference or prior experience
- Are unable to be screened due to their remote location
- Have breast implants
- Are concerned about radiation

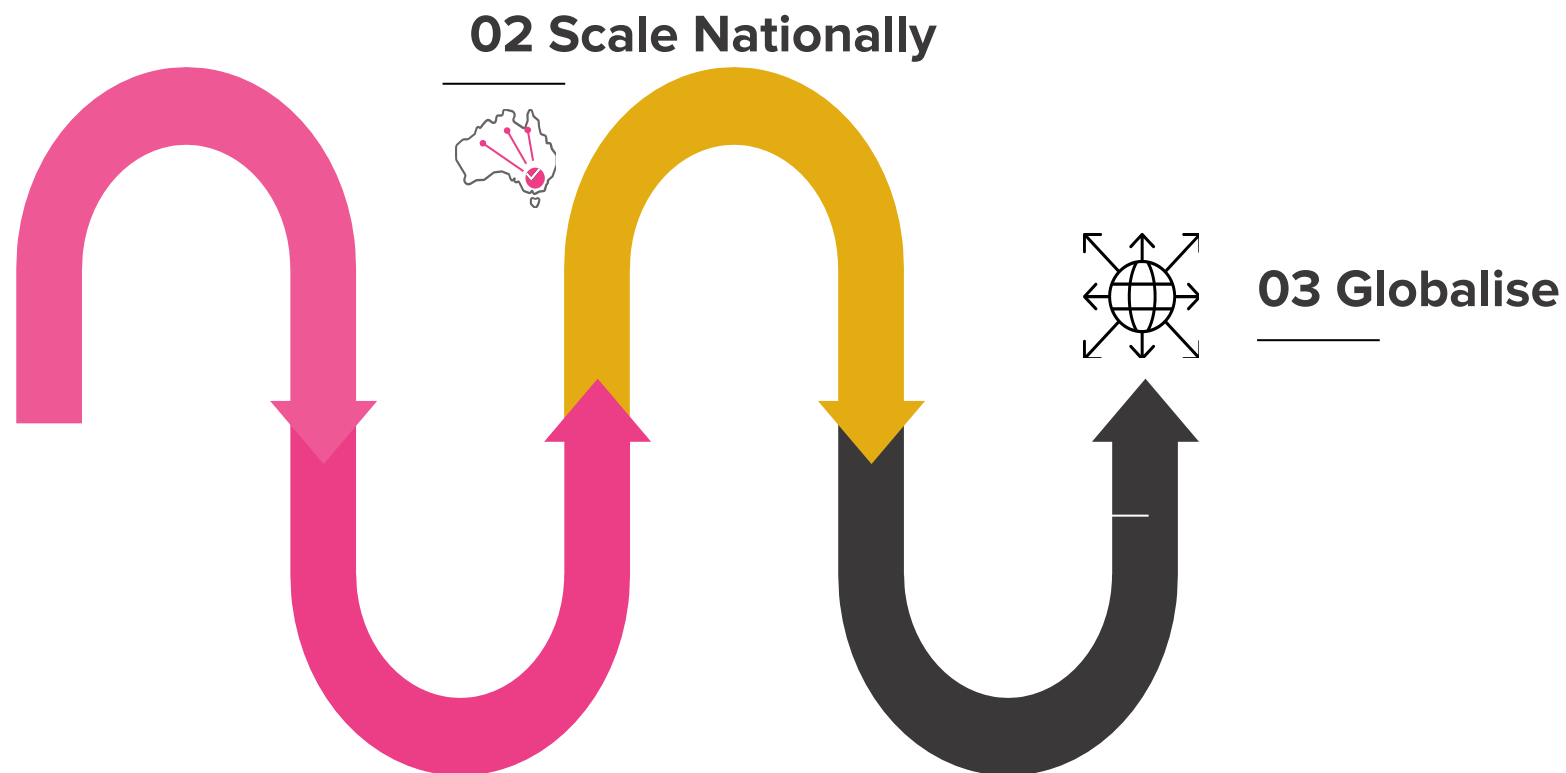
4

### Interval testing

- 8/10,000 women will present with a breast cancer between regular 2 yearly screening.

# COMMERCIAL PATHWAY

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



# BCAL – ACCELERATING TOWARDS COMMERCIALISATION OF BREASTEST®



**BREASTEST®**  
a blood test  
that detects  
breast cancer

- NATA accreditation scheduled for September 2024, a key part of the inhouse IVD regulatory pathway
- *Commercial launch* in Australia in late 2024
- Commercial launch to initially *leverage existing relationship* with sample collection sites, targeting MDT and GPs
- Leverages *AI-driven technology* in BCAL-owned laboratory and operated Biobank, distinguished from competitors by collecting its own samples with strong clinical protocols and governance in place
- Strong and growing IP estate
- 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.**





DRIVING A NEW PARADIGM IN BREAST CANCER DIAGNOSTICS

# Thank you

**Jayne Shaw**  
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**Shane Ryan**  
Chief Executive Officer  
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# APPENDIX

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# 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**

# HIGHLY EXPERIENCED BOARD AND MANAGEMENT



**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 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.

# BREASTEST® HAS A STRONG AND GROWING INTELLECTUAL PROPERTY ESTATES

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.

# FINANCIAL MODEL AND ASSUMPTIONS

} A showcase for the Australian roll-out of BCAL's BREASTEST® highlighting cashflow in CY2025 at commencement of modelling, with significant market penetration



Market Size captured through a phased roll-out plan: 16,000 – 30,000 tests in yr 1, ramping on a yearly basis thereafter



Laboratory capacity will be up to 40,000 tests in year one.  
80 patient samples per run, 6 runs per week per Mass spec machine, aiming for each MS being operational 48 weeks per year



Costing, capex and maintenance are based on professional experience across specimen logistics and collection and processing costs and lab consumables, capital items such as Mass Spec machines and required replacements; personnel costs based on a per Mass Spec assumption