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DRIVING A NEW PARADIGM IN BREAST CANCER DIAGNOSTICS



Annual General Meeting

22 November 2024  
11.00 am (AEDT)

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- Item 1** Executive Chair's **Address**
- Item 2** Financial **Statement and Reports**
- Item 3** **Resolutions**
- Item 4** Chief Executive Officer's **Presentation**
- Item 5** Other **Business**

# ORDER OF PROCEEDINGS

# BOARD OF DIRECTORS



**Jayne Shaw**  
Executive Chair  
and Co-Founder

Trained as a Registered Nurse in the UK, became a Director of Nursing and CEO of two private hospitals upon arriving in Australia.

Jayne has served on various private healthcare boards across specialties such as Cardiology, Orthopedics, and Women's Health, working closely with private equity firms on healthcare transactions both locally and internationally.



**Hon Ron Phillips AO**  
Non-Executive Director  
and Co-Founder

Following 15 years in the NSW Parliament which included serving as Minister for Health and Deputy Leader of the Opposition, Ron developed a successful consulting business in the Health and Aged Care Industry.

Ron recently retired as Chair of the Sydney Local Health District and as Director of Westmead IVF.



**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.

Mark also serves as a senior advisor to organisations including UNEP, UNDP, The Green Finance Initiative, The Nature Conservancy, and the G20 Sustainability Group.



**Jonathan Trollip**  
Independent  
Non-Executive Director

A professional non-executive director with over 30 years of experience in commercial, corporate, governance, legal, and transactional roles.

Jonathan currently serves as Chairman of several ASX-listed companies, is a Fellow of the Australian Institute of Company Directors, and has a strong interest in the not-for-profit sector.



**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.



**John Hurrell PhD**  
Non-Executive Director and  
Consultant

More than 35 years' experience in life sciences & healthcare.

John has developed & successfully commercialised multiple products & services as well as managing start up/early-stage companies.

# COMPANY METRICS



ASX Code

**BDX**

Share Price

18 November 2024

**\$0.11**

Shares on Issue

**358.6M**

Unlisted Options

**4.5M**

Cash

15 October 2024

**\$6.5M**  
(+2.6M R&D rebate)

Top 20 Shareholders

**50%**

Management Shareholding

**20%**



**BCAL** diagnostics



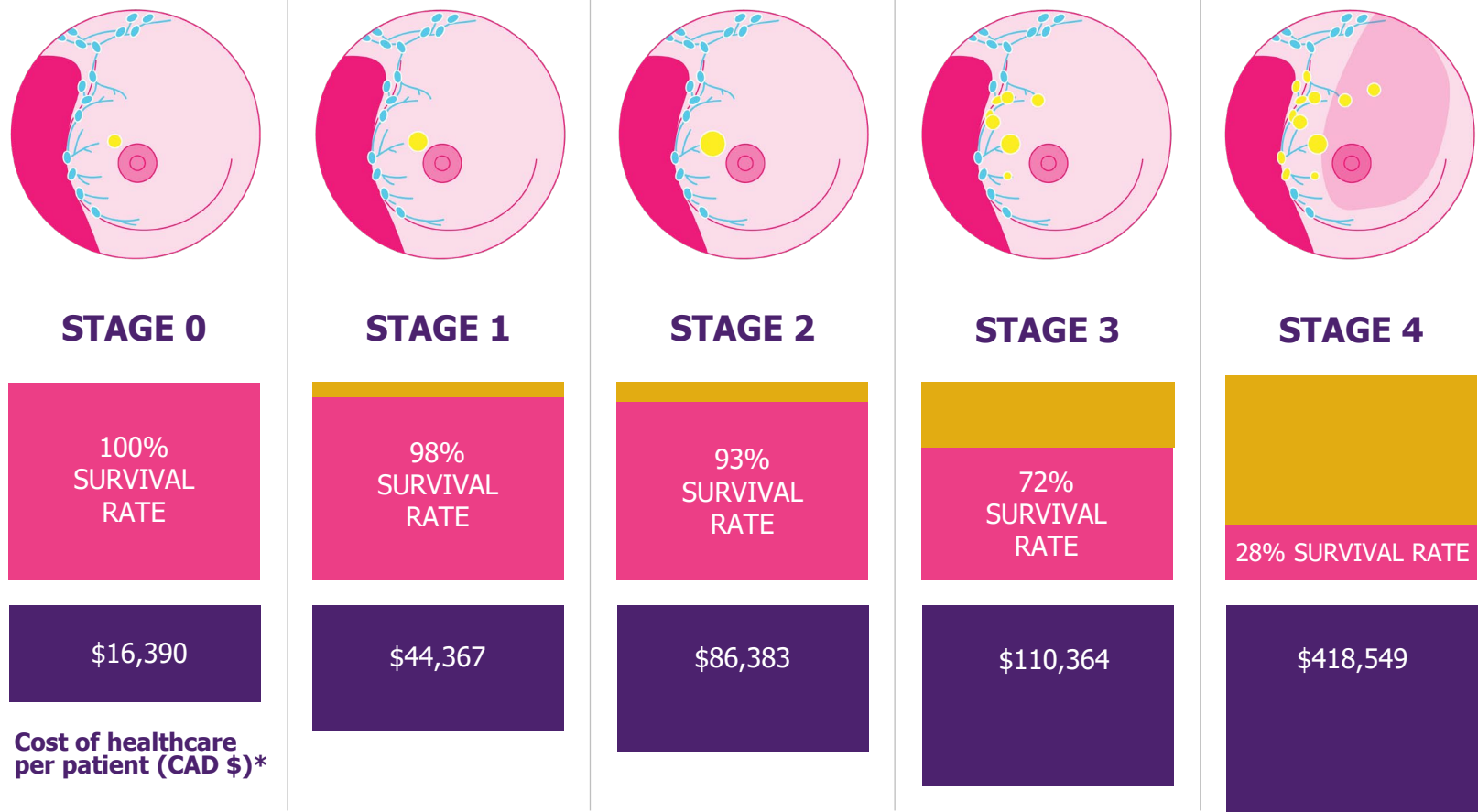
Chief Executive Officer's Presentation

Shane Ryan



# EARLY DIAGNOSIS SAVES LIVES AND COSTS TO THE HEALTHCARE SYSTEM

## BREAST CANCER STAGES



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

Modelling suggest more testing is needed... Annual screening would **reduce mortality rates** by 40% for women between 40-79.

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

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

# THERE IS AN **URGENT NEED** TO GET MORE WOMEN SCREENED IN AUSTRALIA... **BREASTEST® CAN HELP CLOSE THE SCREENING GAP**

**52% / 1.9M**

Australian women  
unscreened  
**ages 50-70**

## Factors affecting screening participation

- Workforce challenges
- Remoteness
- Socioeconomic
- Currently, one size fits all model
- Language(s) spoken at home other than English
- First Nations women
- Cultural
- Fear of radiation

**56% / 4.7M**

Australian women\* fall  
outside the target age-group  
for Breast Screen

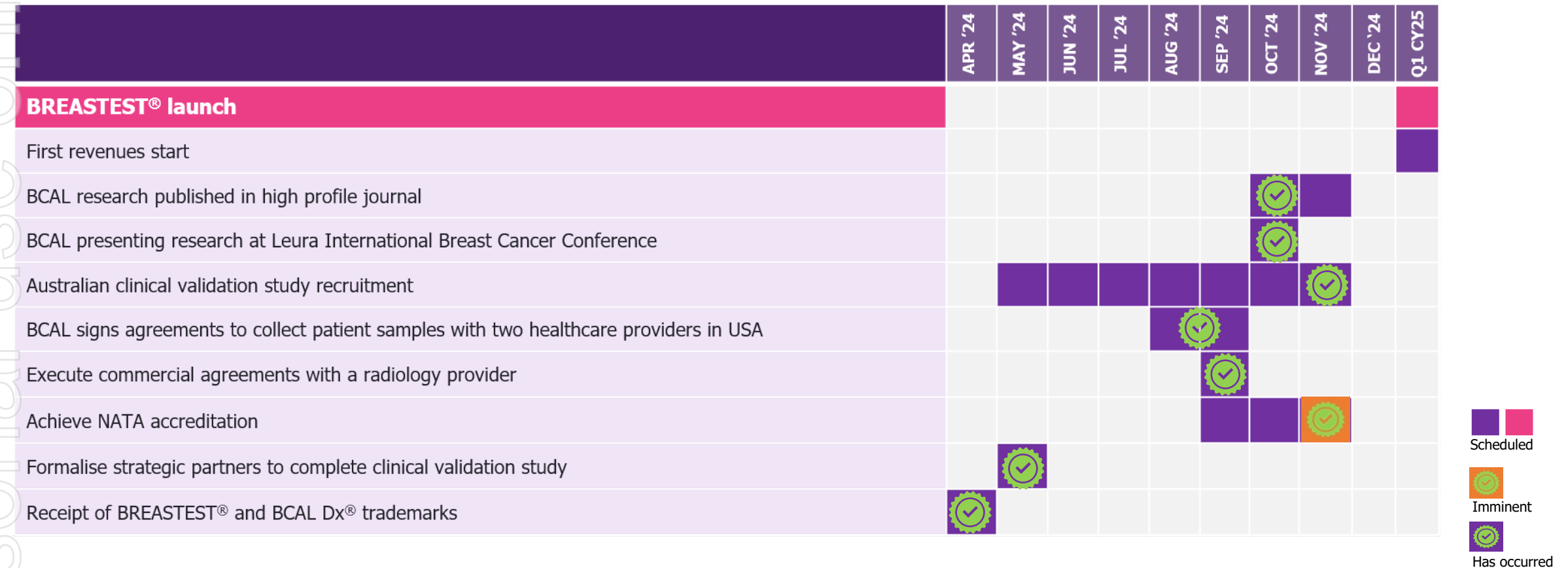
■ 30-49 ■ 75+

\*(aged over 30)



# AUSTRALIAN COMMERCIAL LAUNCH ON TRACK FOR Q1 CY2025, AT THE SYDNEY BREAST CLINIC

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



## Product development

Completed clinical study in collaboration **with Precion Inc of North Carolina (USA)**. Study included 656 samples, being 390 breast cancer patients and 266 healthy controls and achieved a sensitivity of **90%** and a specificity of **85.5%**.

Ongoing analysis of the analytical validation studies (SENSIBLE), examining the performance of BREASTEST® in an Australian cohort of 773 patients.

The Australian clinical validation study (~500 patients) has completed recruitment and will analysed prior to commercial launch of product.

## NATA accreditation

NATA assessment of the North Ryde clinical laboratory occurred on 30 September 2024. BCAL has implemented the necessary procedures and quality systems to meet the rigorous requirements for **NATA accreditation**.



**Accreditation  
Matters**

## Sample collection progress

**Over 5,000 samples** from biopsy-confirmed breast cancer patients and healthy controls have been collected from Europe, Australia, and the U.S.

To further enhance sample diversity, BCAL has partnered with the **KIMS Institute** and Indo American Hospital in Hyderabad, India.

## Growing intellectual property

A European patent was granted and Australian patent accepted, bringing the number of **granted/accepted patents to 24**.

Secured trademark registration for **BREASTEST® in Australia, UK and Europe** with applications pending in US, China, India, Canada, South Korea and NZ.

# CORPORATE HIGHLIGHTS

NOVEMBER 2024



## Clinical Advisory Board - Australian breast cancer experts

Established a Key Opinion Leader Network (KOL) comprising **nationally recognised breast cancer specialists** who are committed to collaborating with BCAL and being champions for further development of BCAL scientific program and Australian market launch.

## First peer-reviewed publication

BCAL continued to enhance its scientific profile through the **publication in the International Journal for Molecular Science**, [click here for journal article](#)

*Discovery of Plasma Lipids as Potential Biomarkers Distinguishing Breast Cancer Patient from Healthy Controls.*

## Capital raise

### **\$10.5M capital raise**

Fantastic support from existing and new shareholders from Australia, Singapore, and Hong Kong. Providing BCAL with the capital required for product development and soft launch of BREASTEST®

## First Commercial Partner

Agreement in place with **the Sydney Breast Clinic** will be the first multidisciplinary Breast Cancer Clinic to offer BREASTEST® to women in Australia.

# US RESEARCH AND PRODUCT DEVELOPMENT COMMENCED

## Laboratory

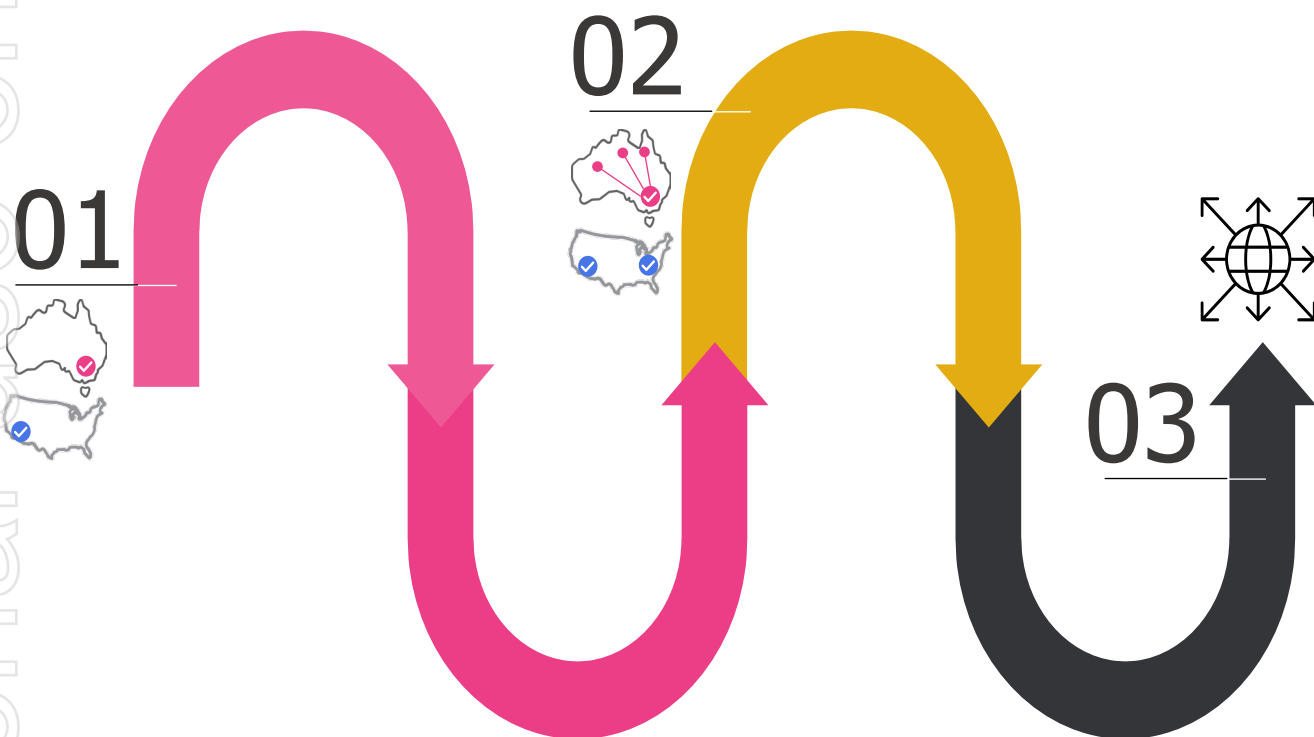
- Established BCAL US subsidiary, lease of US premises secured, and key laboratory equipment purchased
- The US program offers BCAL an opportunity to accelerate and validate new products on US patient centric data and gain an in-county understanding of the US diagnostics market
- Collaboration with US Physicians is progressing at the first two partner sites, Michigan and Chicago
- Research recruitment of patient samples has commenced at Endeavour Health, Chicago

## People

- BCAL US officeholders include Shane Ryan as President and BCAL directors Jayne Shaw, Dr. John Hurrell and Jonathan Trollip as directors of BCAL US
- The former Chief Technology Officer of Precion, Dr. Klaus-Peter Adam, joined BCAL US, as full-time Director of US Research and Product Development
- Appointed Consultant, Cory Dunn (marketing and business development) who brings a wealth of US marketing experience and comprehensive knowledge of the US breast cancer network

# COMMERCIAL PATHWAY

**BCAL roadmap to commercial launch underpinned by a reproducible lipidomic platform and a proprietary biobank of growing data.**



## Australian Launch & US foundations

- 01**
- Launch of BREASTEST® in Australia generating first revenues in Q1 CY 2025
  - Initial focus on NSW & VIC with existing strong clinical leadership and commercial partners
  - Commercial partnership with Sydney Breast Clinic in place, and positive discussion underway with additional commercial partners nationally, aiming for mass market penetration
  - Market Access program accelerates education & awareness with Breast Surgeons, Breast Clinics, GP's, radiology and pathology providers, Breast care Nurses, Advocacy Groups, and Government agencies
  - Collaborate with US Physicians: partner sites established in MI and IL
  - Initiate discussions with US CLIA-approved lab

## Scale nationally

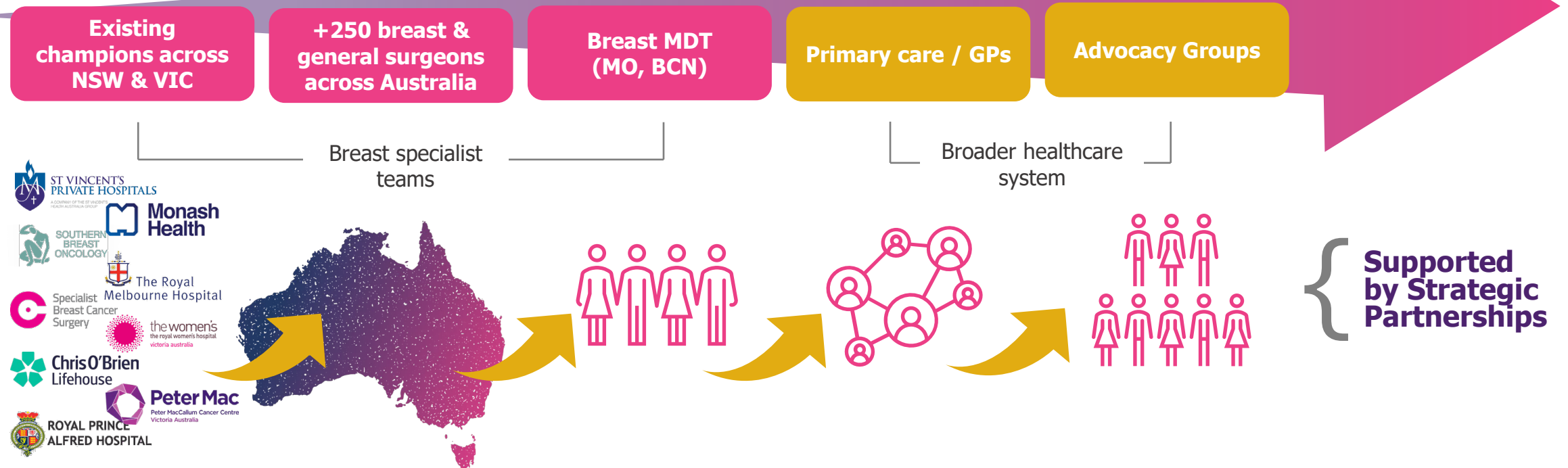
- 02**
- Nationwide market access initiatives to take BREASTEST® across Australia
  - Patient sample processing occurs at BCAL Sydney laboratory
  - Publish in scientific literature the clinical and utility performance of BREASTEST® to underpin other market launches
  - Consolidate and continue to grow volume in Australia

## Build on US program

- 03**
- BCAL Diagnostics, Inc established in North Carolina, US
  - Continue US specimen collection for US validation
  - Prepare for commercial launch in the US
  - Expand intended use and develop products on BCAL's platform for other cancers

# AUSTRALIAN MARKET ACCESS PLAN CY2025

## BREASTEST® ADOPTION



## Rollout timeframes:

Q1: NSW

Q2: NSW & VIC

Q3: NSW & VIC +1

Q4: National



# MARKET SEGMENTATION

## FOUR INITIAL KEY TARGET SEGMENTS



### 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



### Dense breast tissue

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

- Younger women tend to have more dense breast tissue.



### 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



### Interval testing

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

# CLINIC ADVISORY BOARD

} Eminent and influential Breast Clinicians form a Breast Cancer Clinical Advisory Board to enhance trust, provide advice and inform the BCAL program



**Dr David Speakman**

Former Chief Medical Officer at the Peter MacCallum Cancer Centre, and joint Clinical Director at BreastScreen Victoria



**Prof Bruce Mann**

Director of Breast Cancer Services for the Royal Melbourne and Royal Women's Hospitals. He is also the Director of Research at Breast Cancer Trials



**Dr Corinne Ooi**

Head of the Monash Health Breast Unit and VMO at Monash BreastScreen.



**A/Prof. James French**

Head of Breast Surgery at the Westmead Breast Cancer Institute



**Prof. Elisabeth Elder**

Specialist Breast Surgeon and Head of Research at the Westmead Breast Cancer Institute.



**A/Prof. Cindy Mak**

Head of Department at Chris O'Brien Lifehouse and Royal Prince Alfred Hospital



**Dr Samriti Sood**

Specialist Oncoplastic with appointments at Royal North Shore and the Mater Hospital.



**A/Prof. Gillian Lamoury**

Radiation Oncologist and member of the Strategic Advisory Group for BCNA



**Dr Sally Baron-Hay**

Medical Oncologist specialising in Breast Cancer



**Prof. Mary Rickard OAM**

Breast Imaging Radiologist, Chief Medical Officer and Co-Founder of DetectedX. A pioneer at BreastScreen NSW.

# HIGHLY EXPERIENCED LEADERSHIP TEAM

} With commercial expertise to drive BREASTEST® launch



**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.



**Alexandra Feetham BCom**  
Head of Innovation & Strategy

An expert in innovation, strategy, and product development across healthcare, biotechnology, and finance. Alex brings over a decade of experience in corporate development, oncology strategy, and transformative technologies.



**Dr David Speakman**  
Medical Laboratory Director &  
Chair Clinical Advisory Board

Is a leading Breast Surgeon and the former Chief Medical Officer at the Peter MacCallum Cancer Centre. David brings a wealth of experience, guiding our clinical program and market entry.



**Cory Dunn M.S., M.Ed**  
Marketing – US Operations

Brings a wealth of US marketing experience and comprehensive knowledge of the US breast cancer network. Cory was previously the Vice President, Marketing at PreludeDx.



**Kim Kirkham**  
National Clinical Program Director

With a foundation in oncology nursing, Kim has over 18 years oncology experience. More recently, Kim has led the market access strategy for the successful introduction of DCISionRT across Australia.



**Dr Mark David PhD**  
Head of Aus Research and Product  
Discovery

A leading researcher in the field of lipidomics, Mark has worked in both academia and industry, with a PhD in metabolomics/lipidomics from Imperial College London.



**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.



**Kathy Koskiris BSc, MBA**  
Director of 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 Klaus-Peter Adam**  
Director of US Research and Product  
Development

Scientific thought leader and former CTO of Precion. Klaus-Peter has more than 20 years experience in developing small molecule products in the US market.



**Guy Robertson**  
Chief Financial Officer & Company  
Secretary

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 a number of ASX/AIM listed companies.

# PILLARS TO SUCCESS IN THE NEXT 12 MONTHS



## Market Access Strategy

- Our main focus in the immediate future is delivering BREASTEST® to the Australian market.
- Kim Kirkham, BCAL's National Clinical Program Director, has developed a **comprehensive market access plan**. This will be rolled-out and leverage the **extensive Breast cancer network** knowledge gained from BCAL's Key Opinion Leaders (KOL) and senior management. Landing agreements with commercial partners that have national scale **will enable BCAL to scale, grow and drive BREASTEST® adoption**.

## Key opinion leader network

- A key enabler to BCAL's **market access strategy**, the KOL comprises nationally recognised breast cancer specialists who are committed to collaborating with BCAL to address clinical utility ahead of BREASTEST® commercial launch. BCAL will strategically grow the KOL network as it moves towards a national program.

## Industry partnerships

- BCAL will **strategically partner and execute agreements** with radiology partners and breast cancer clinics that will **accelerate market penetration** and growth

## Talent and Team

- BCAL has now got **a great team in place** to accelerate the scientific program and to take the product to market in Australia, without placing additional strain on the **current financial burn-rate**. The clinical laboratory team will refine the sample turnaround times to improve efficiency and cost of running the test, and the clinical research team will combine with our KOL's to publish a number of high impact publications building the evidence to drive BREASTEST® adoption.

## US Program

- BCAL will build out a network of sites and physicians to collect a high number of samples in the US, that will **set the Company up for commercial launch**.
- A number of commercial partners will be identified that will guide BCAL through the regulatory and re-imbursement requirements for launch of a Laboratory Developed Test (LDT).

## ITEM 5 Other Business

# QUESTIONS





DRIVING A NEW PARADIGM IN BREAST CANCER DIAGNOSTICS



# Thank you

**Jayne Shaw**  
Executive Chair  
[jshaw@bcaldiagnostics.com](mailto:jshaw@bcaldiagnostics.com)

**Shane Ryan**  
Chief Executive Officer  
[sryan@bcaldiagnostics.com](mailto:sryan@bcaldiagnostics.com)