



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%

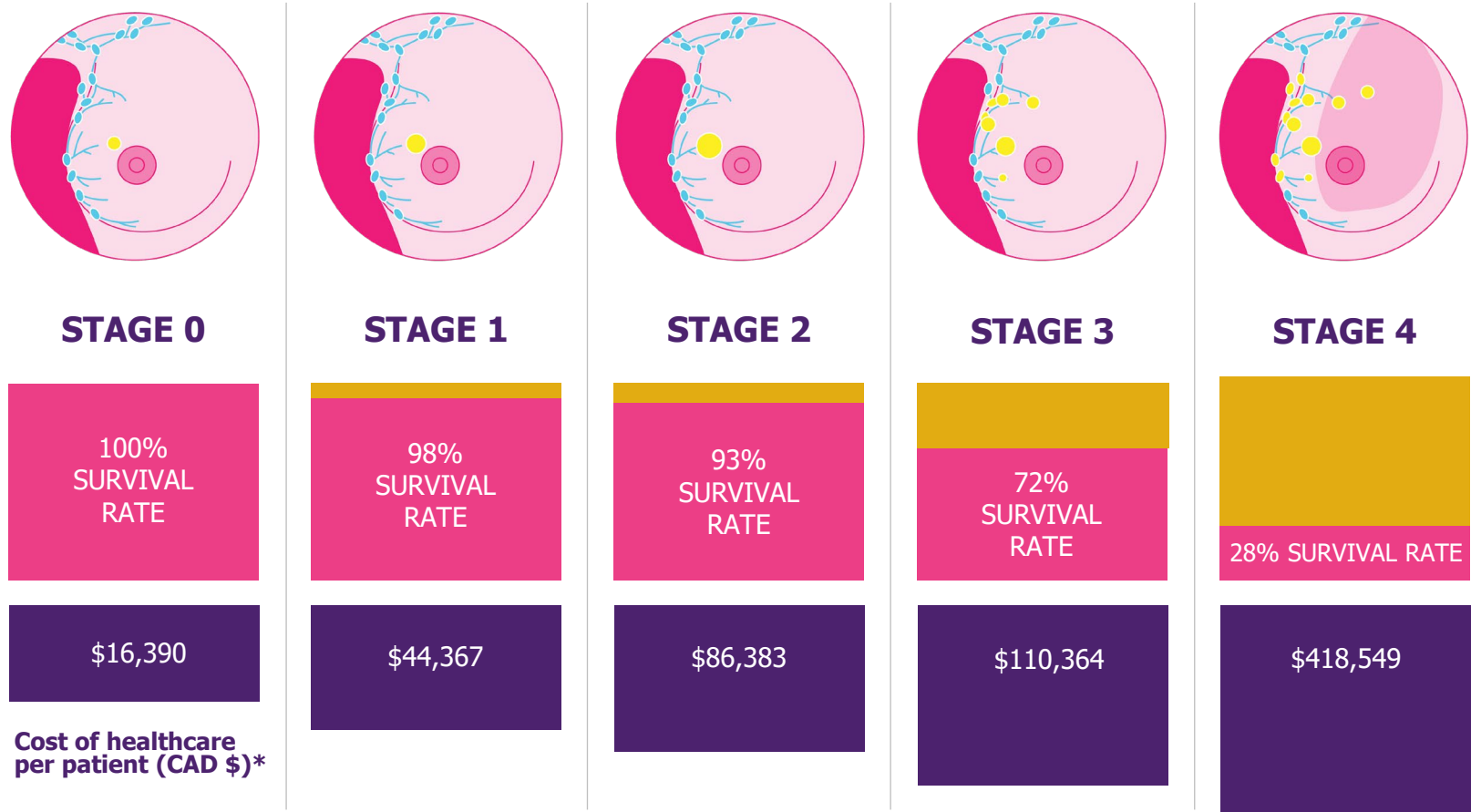


Chief Executive Officer's Presentation

Shane Ryan

EARLY DIAGNOSIS SAVES LIVES AND COSTS TO THE HEALTHCARE SYSTEM

BREAST CANCER STAGES



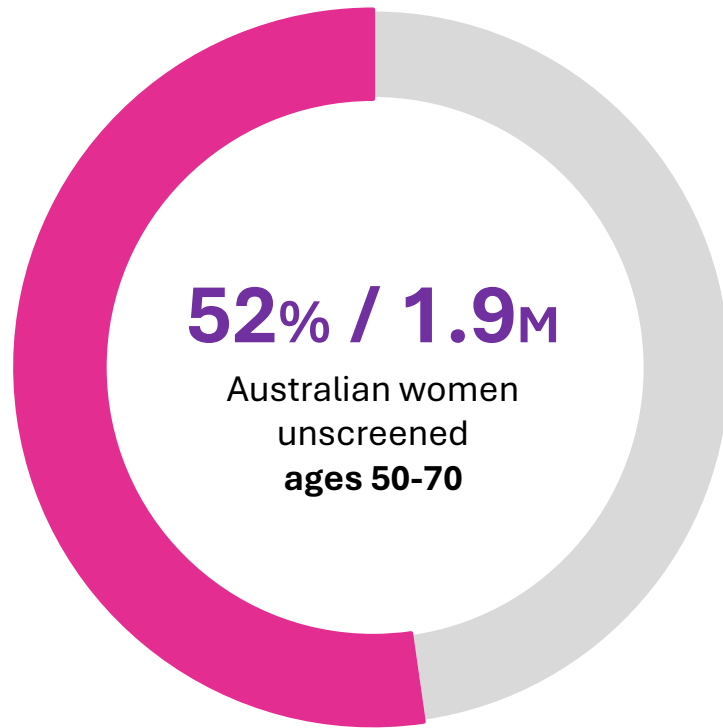
BCAL is focused on **improving the outcomes** for women with breast cancer

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>

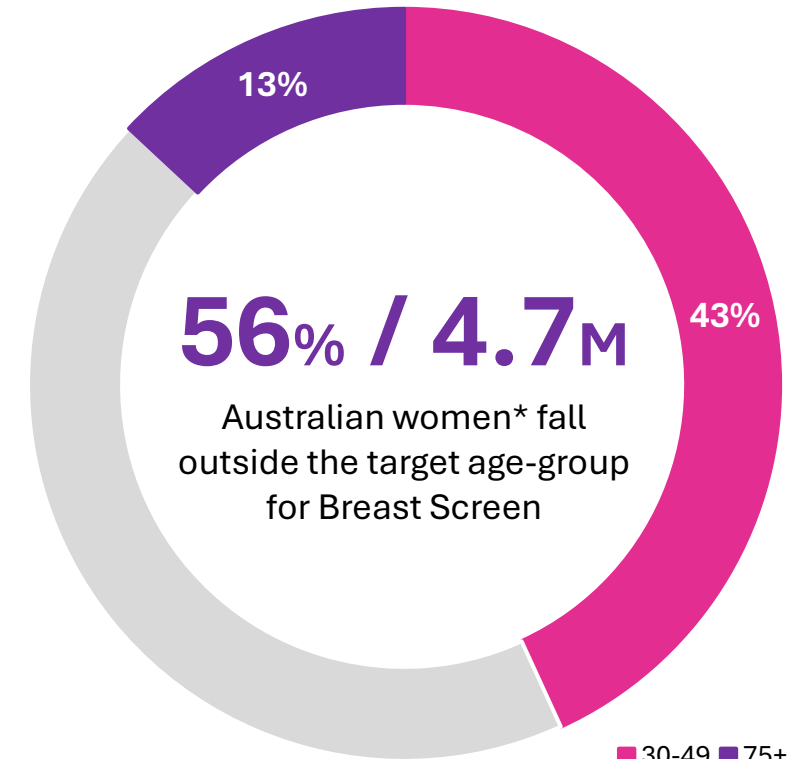
*Article: Capturing the True Cost of Breast Cancer Treatment: Molecular Subtype and Stage-Specific per-Case Activity –Based Costing, 2023

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



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



*(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.

	APR '24	MAY '24	JUN '24	JUL '24	AUG '24	SEP '24	OCT '24	NOV '24	DEC '24	Q1 CY25
BREASTEST® launch										
First revenues start										
BCAL research published in high profile journal							Has occurred	Scheduled		
BCAL presenting research at Leura International Breast Cancer Conference							Has occurred			
Australian clinical validation study recruitment		Scheduled	Scheduled	Scheduled	Scheduled	Scheduled	Scheduled	Has occurred		
BCAL signs agreements to collect patient samples with two healthcare providers in USA					Has occurred					
Execute commercial agreements with a radiology provider						Has occurred				
Achieve NATA accreditation						Scheduled	Scheduled	Imminent		
Formalise strategic partners to complete clinical validation study		Has occurred								
Receipt of BREASTEST® and BCAL Dx® trademarks	Has occurred									

Scheduled

Imminent

Has occurred

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.

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

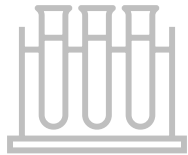
\$10.5M capital raise

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

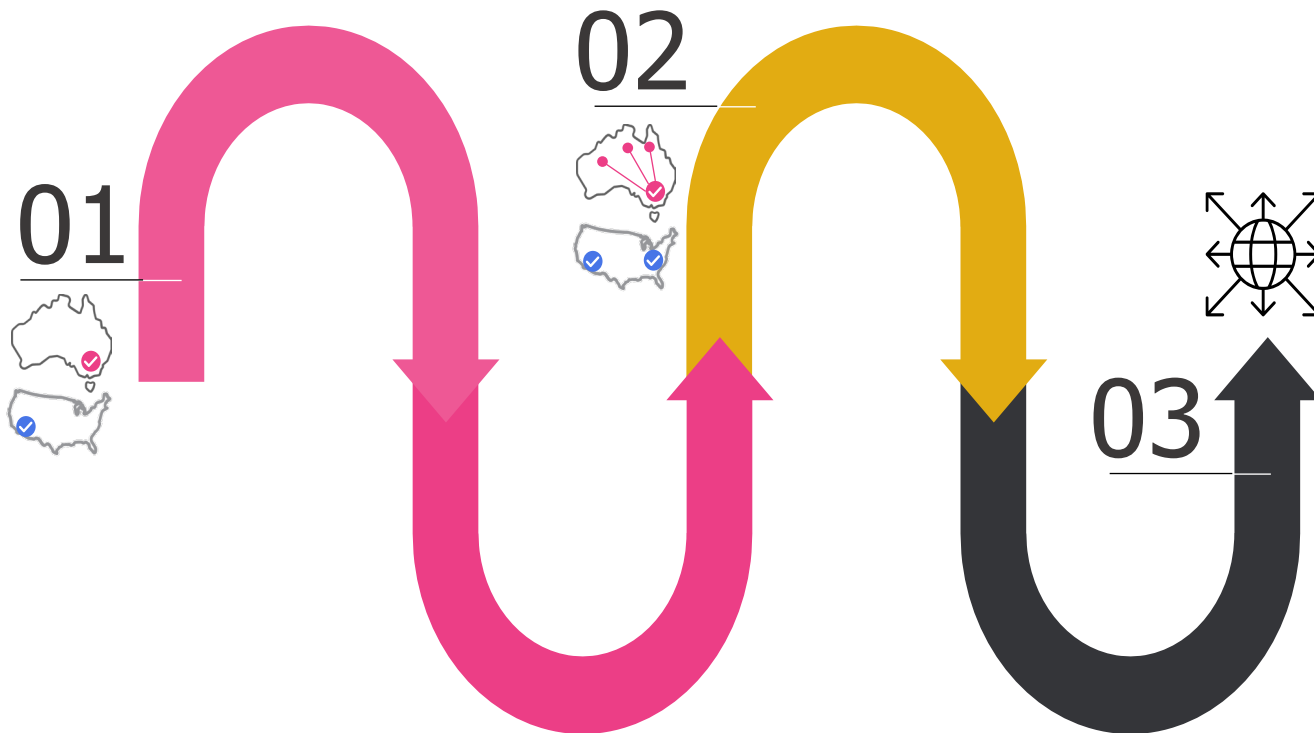


People

- 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

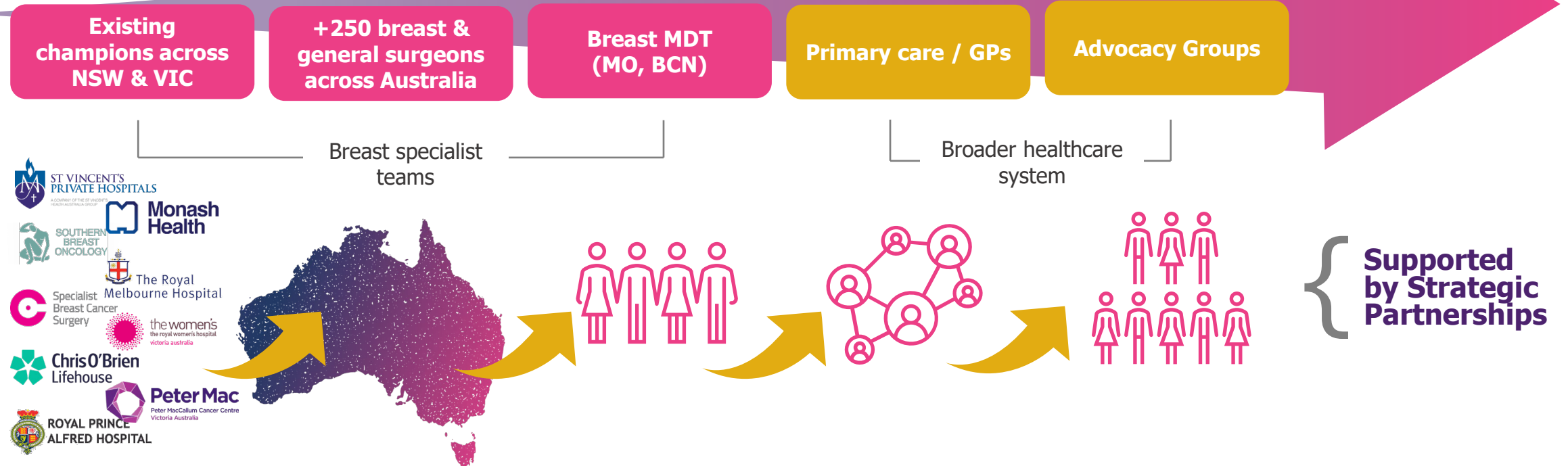
03

Build on US program

- 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;

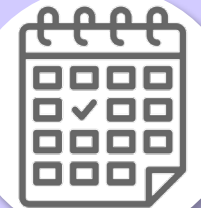
- Younger women tend to have more dense breast tissue.



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

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Shane Ryan

Chief Executive Officer

sryan@bcaldiagnostics.com

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