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DRIVING A NEW PARADIGM IN BREAST CANCER DIAGNOSTICS



Spark+ Australian Equities Day Presentation

Executive Chair, Jayne Shaw

September 2024

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COMPANY METRICS



ASX Code

BDX

Share Price
16 September 2024

\$0.12

Shares on Issue

358.6M

Unlisted Options

4.5M

Cash
31 August 2024

\$8.8M

Top 20 Shareholders

52%

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



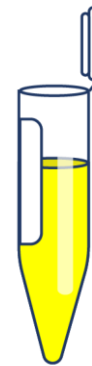
Whole Blood



Plasma
Erythrocytes

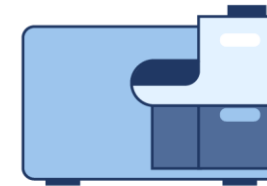
Pre-processing: sample spin, separate and freeze

TRANSIT

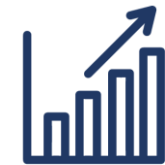


Sample preparation:
plasma lipid extraction

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



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A GLOBAL 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, BreastCancer.org

\$2.3B

2023 to

\$6.9B

2033

Persistence Market Research

On average

57 People

are or will be diagnosed with breast cancer everyday

BCNA

2.1 Million Mammograms in AUS in 2021

BSA

310,720

cases of breast cancer are expected to be diagnosed in the US in 2024

2024, American Cancer Society

\$70M

2024 to

\$108M

2029

Mordor intelligence

37.6%

Of Singaporean women aged 50 to 69 reported getting mammograms every 2 years

2023, The Straits Times, Singapore

52.3 Million Mammograms in 2019 in the US

CDC

Women have a







1 in 7

chance of being diagnosed with breast cancer over their lifetime

NCBF

BREASTEST® WILL BE USED AS A SCREENING TOOL

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SCREENING		DIAGNOSTICS			
					
BREASTEST®	Mammography	Ultrasound	3D Mammography	Contrast enhanced mammography	MRI
<ul style="list-style-type: none"> Simple blood test Solves challenges with imaging dense breasts Highly accessible Cost effective Safe 	<ul style="list-style-type: none"> Painful procedure Less effective for dense breasts Expensive infrastructure, reduces access Radiation exposure 	<ul style="list-style-type: none"> Used for mass/lesion differentiation, no diagnostic capability Not suitable as population screening tool 	<ul style="list-style-type: none"> Painful procedure Improved sensitivity Expensive infrastructure, reduces access Radiation exposure Not suitable as population screening tool 	<ul style="list-style-type: none"> Painful procedure Improved sensitivity Expensive infrastructure, reduces access Radiation exposure Risk of reaction to contrasting agent Not suitable as population screening tool 	<ul style="list-style-type: none"> High sensitivity High cost, limited availability Safer than other imaging technologies Not suitable as population screening tool

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 or 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

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 24¹)

Ongoing generation of analytical data to validate BREASTEST®

ANALYTICAL VALIDATION STUDIES

CLINICAL VALIDATION STUDY
Multi-center observational study

BREASTEST®
soft launch

Commercialise
test and supply
in-house

¹NATA accreditation audit scheduled for 30 September 2024

MARKET ACCESS: AUSTRALIA SOFT LAUNCH

Launch of BREASTEST® in Australia late 2024 & first revenues

01



NSW & VIC launch

- Initial focus on Sydney and Melbourne
- Leveraging existing sample collection sites, prioritising those who can convert to commercial partners
- Targeting breast cancer Multidisciplinary Teams (MDT) and Primary Care Providers (GP's)



02



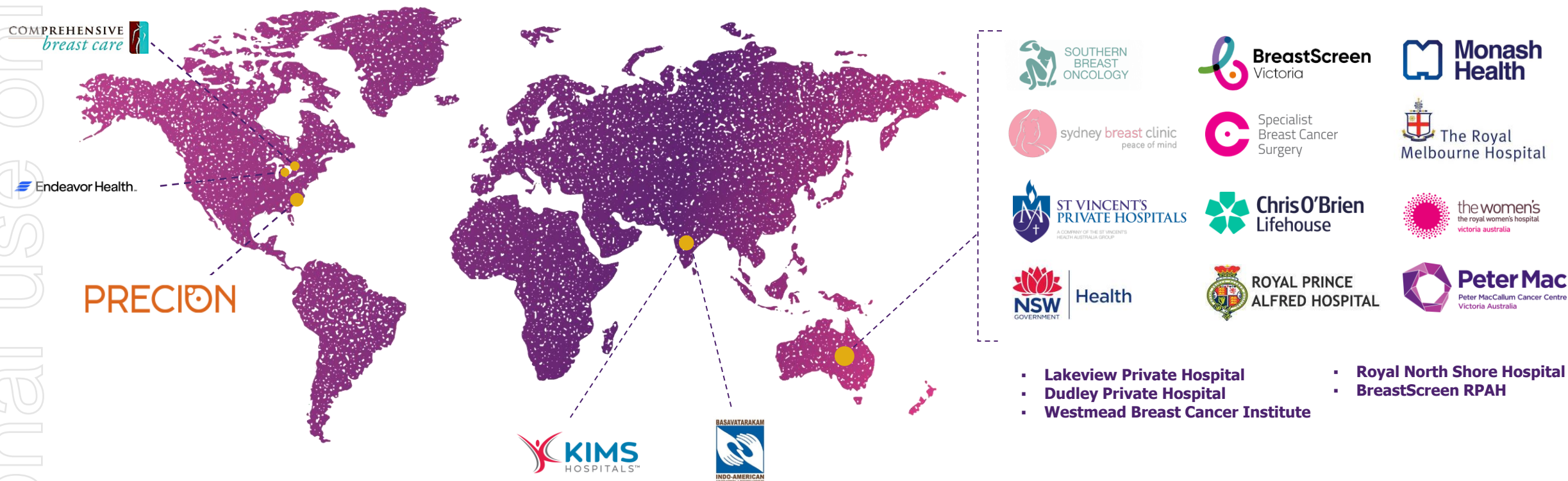
Scale nationally

- Focus on raising awareness in CY2024
- Nationwide market access initiatives to take BREASTEST® across Australia

Strategy

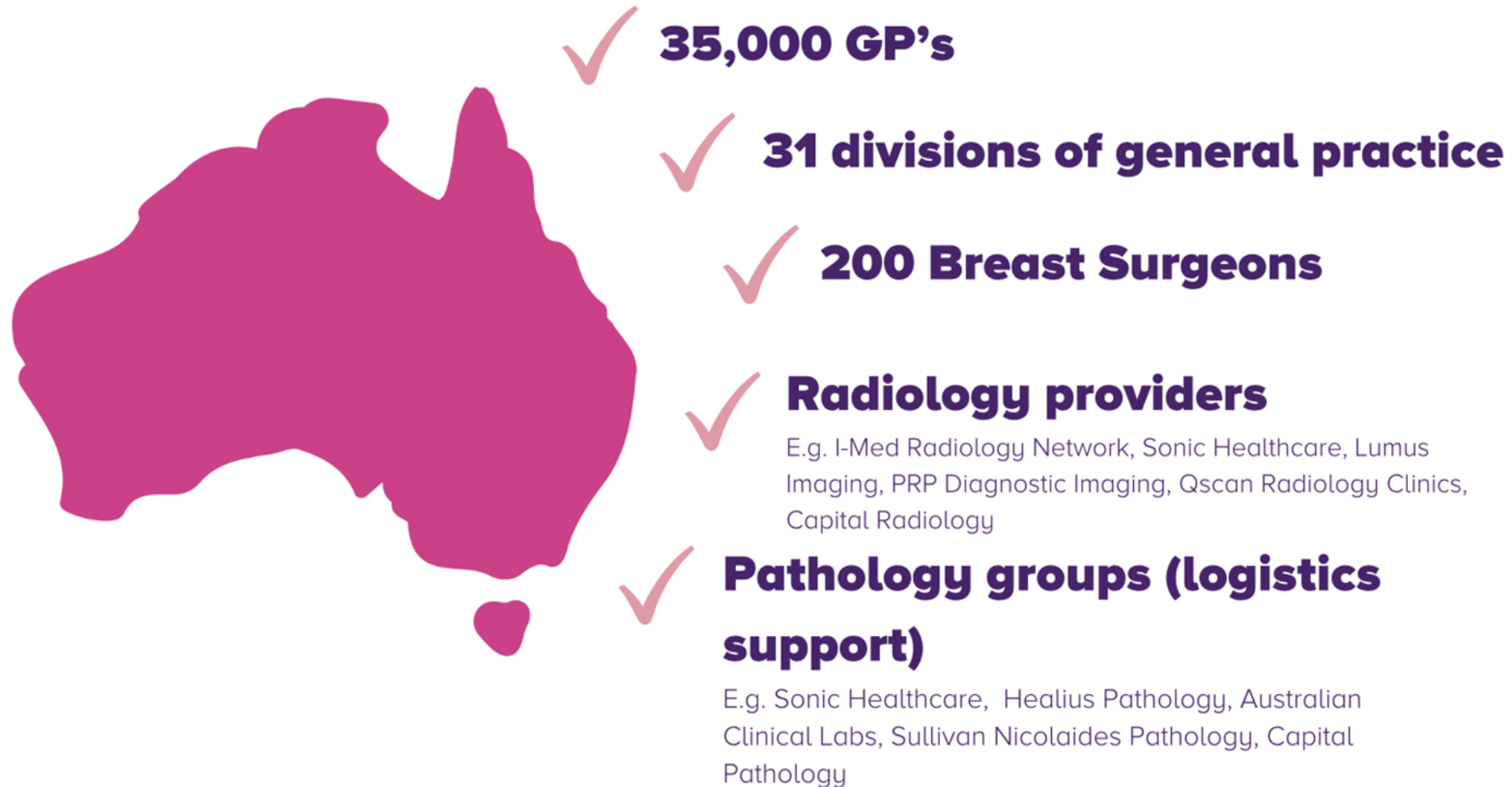
- Who: KOLs and Market Access Team
- Matrix style: Including 1:1 meetings, conference presentations, dinners, educational webinars
- Accelerate education & awareness: Breast surgeons, Breast Clinics, GP's radiology and pathology providers, breast care nurses, advocacy groups and govt agencies
- Develop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

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

AUSTRALIAN DISTRIBUTION LANDSCAPE



COMPREHENSIVE EDUCATION PROGRAM

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

Community

- Social media campaigns and influencers
- Community health seminars
- Collaborations with women's health organisations

Advocacy

- Continued support and collaboration with advocacy groups such as Breast Cancer Network Australia, So Brave, Sydney Breast Cancer Foundation and Pink Hope

Referral network

- Build a robust referral network by collaborating with top hospitals, clinics, and health centers
 - Use CRM tools to manage and streamline referrals.
- Establish a feedback loop with referring physicians to ensure seamless patient care

GPs

- Professional seminars and workshops
- Continuing Medical Education (CME) credits
 - Detailed informational brochures and clinical evidence

Breast Surgeons

- Direct presentations at surgical conferences
- Peer-reviewed journal publications
- Collaborative case studies and clinical trial results

Lab diagnostics network / Pathology groups / Radiology providers

- Patient management software programs for GP's & Specialists such as Medical Director, HCN, Sonic Software, Best Practice, Medtech Evolution

Digital market entry strategies

- Primary care education

US OPERATIONS 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

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, to join BCAL US, as full-time Director of US Research and Product
- Appointed Ms Cory Dunn (marketing and business development) who brings a wealth of US and Australian marketing experience and comprehensive knowledge of the US breast cancer network

Funding

- As result of the recent \$10.5 million capital raising, BCAL US has been established and can operate over the short-term without needing to raise any further capital

PUBLICATIONS AND MANUSCRIPTS

Research & Publications

- Peer-reviewed publications are a crucial part of developing novel technologies like BREASTEST®
- BCAL is working on multiple research articles detailing the discovery and development of BREASTEST®
- The first original research paper is expected to be published in a respected journal during Q1 FY25
- Four additional peer-reviewed publications are planned for submission by the end of FY25 to support market access strategies and global regulatory submissions

Presentations & Conferences

- In July 2023, Associate Professor Sanjay Warrior presented BCAL's advancements and the potential integration of BREASTEST® at the Breast Cancer Trials Annual Scientific Meeting
- BCAL also presented research findings at the American Association of Clinical Chemists (AACC) and the Australasian Association for Clinical Biochemistry and Laboratory Medicine (AACB) conferences
- In December 2023, BCAL was recognized for its poster presentation on an AI-based breast cancer detection model using Plasma Lipidomic Signature at the prestigious San Antonio Breast Cancer Conference, showcasing their pioneering research to leading breast cancer experts globally

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.

SOFT COMMERCIAL LAUNCH ON TRACK FOR LATE 2024

} 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	JAN '25
BREASTEST® launch										
First Revenues										
BCAL research published in high profile journal										
BCAL presenting research at Leura International BCC.										
Australian 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										
Achieve NATA accreditation										
Formalise strategic partners to complete clinical validation study										
Receipt of BREASTEST® and BCAL Dx® trade marks										

BCAL – INVESTMENT HIGHLIGHTS



BREASTEST®
a blood test
that detects
breast cancer

- **NATA accreditation** scheduled for September 2024, a key part of the inhouse IVD regulatory pathway
- **Commencement of US operations** in September 2024
- **Soft 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

Executive Chair

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Shane Ryan

Chief Executive Officer

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APPENDIX

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FINANCIAL YEAR 2024 HIGHLIGHTS



Scientific progress

- Completed a clinical study in collaboration with Precion Inc of North Carolina (USA). The study included a total of 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), which is examining the performance of BREASTEST® in an Australian cohort of 773 patients
- The clinical validation study is recruiting well and will be completed prior to commercial launch of product

Laboratory accreditation

- BCAL has implemented the necessary procedures and quality systems to meet the rigorous requirements for NATA accreditation with the final audit scheduled for 30 September with accreditation expected following this

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

FINANCIAL YEAR 2024 HIGHLIGHTS



Intellectual property

- The Company's IP portfolio continues to grow, with several patents and trademarks progressing through to grant and registration in a number of targeted jurisdiction. A European patent was granted, increasing the number of patents granted to eight
- Secured trademark registration for BREASTEST® in Australia with applications pending in US, UK, Europe, China, India, Canada, South Korea and NZ

Key opinion leader network

- Established a Key Opinion Leader Network (KOL) comprising nationally recognised breast cancer specialists who are committed to collaborating with BCAL to address intricate patient needs ahead of BREASTEST® commercial launch

Industry participation to broaden exposure

- BCAL continued to enhance its scientific profile through active participation in key industry conferences and through the establishment of community partnerships

Capital raise

- BCAL has the funds in place to complete the final stages of its launch strategy, following its oversubscribed \$10.5M capital raise, as it works with its network of Key Opinion Leaders, commercial, and community partners

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.



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.



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.

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

Chief Medical Officer at the
Peter MacCallum Cancer
Centre



Prof Bruce Mann

Director of Breast Cancer
Services for the Royal Melbourne
and Royal Women's Hospitals



Dr Corinne Ooi

VMO at Monash BreastScreen
and a Foundation Member of
BreastSurgANZ



A/Prof. James French

Head of Breast Surgery at the
Westmead Breast Cancer
Institute



Prof. Elisabeth Elder

Head of Research at the
Westmead Breast Cancer
Institute.



A/Prof. Cindy Mak

Breast Surgeon,
Chris O'Brien Lifehouse



Dr Samriti Sood

Breast Oncoplastic
Surgeon



**A/Prof. Gillian
Lamoury**

Radiation Oncologist



Dr Sally Baron-Hay

Medical Oncologist



Dr Mary Rickard OAM

Breast Imaging Radiologist,
Chief Medical Officer and Co-
Founder of DetectedX