

BCAL diagnostics

INVESTOR PRESENTATION Singapore & Hong Kong

ADVANCING BREAST CANCER SCREENING WITH A NON-INVASIVE BLOOD TEST

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COMPANY METRICS		9
ASX Code	BDX	
Share Price 21 Mar 2025	\$0.098	
Shares on Issue	365.9M	
Unlisted Options	4.5M	
Cash 31 December 2024	\$7.0M	
Top 20 Shareholders	52%	

AGENDA

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INTRODUCING BREASTEST *plus*™

ADVANCING BREAST CANCER SCREENING WITH A NON-INVASIVE BLOOD TEST



BREASTEST *plus*[™] - EARLY DETECTION NON-INVASIVE BLOOD TEST





BCAL Diagnostics is an Australian and US-based biotechnology company dedicated to advancing early and accurate breast cancer detection

Our Mission: For over a decade, BCAL has been committed to developing innovative, accessible technologies that enhance breast cancer screening and potentially reduce follow-up investigations including biopsy

Our goal is to empower women and their clinicians with reliable diagnostic tools that improve early detection and streamline the screening process

BREASTEST *plus*[™] LAUNCHED MARCH 2025

BREASTEST *plus*[™]

A blood test to complement breast imaging results and rule out the presence of breast cancer



BREASTEST plusTM and imaging for comprehensive screening



BREASTEST *plus*[™] **IS THE** 1ST **PRODUCT IN THE BREASTEST**[®] **RANGE**

BREASTEST *plus*[™] TEST PERFORMANCE



BREASTEST *plus*[™] is an ideal precision medicine test to complement breast imaging procedures and clinical factors to confidently rule-out breast cancers in women with a higher breast density

BREASTEST *plus*[™] performance in intended population category D

 SENSITIVITY
 SPECIFICITY

 91%
 49%

BREASTEST *plus*[™] performance in intended population category C

SENSITIVITY	SPECIFICITY
86%	22%







ADDRESSING AN UNMET NEED

ADVANCING BREAST CANCER SCREENING WITH A NON-INVASIVE BLOOD TEST



RISING GLOBAL INCIDENCE OF BREAST CANCER





¹Breastcancer.org Breast cancer Facts and Statistics est. 2025 figures <u>https://www.breastcancer.org/facts-statistics</u> ² World Cancer Research Fund; est 2022 figures <u>https://www.wcrf.org/preventing-cancer/cancer-statistics/breast-cancer-statistics</u> ³ Current and future burden of breast cancer: Global statistics for 2020 and 2040; National Library of Medicine. <u>https://pmc.ncbi.nlm.nih.gov/articles/</u> ⁴ Breast Cancer Statistics, Breast Cancer Trials est. 2024 figures <u>https://www.breastcancertrials.org.au/breast-cancer-resources/breast-cancer-statistics</u>

⁵ Breast Cancer Diagnostics Market Size, Share, and Trends 2025 to 2034, https://www.pecedenceresearch.com/breast-cancer-diagnostics-market
 ⁶ Centre for Health Protection, Breast Cancer figures based on 2022 data, www.ch.gov.hk
 ⁷ Based on figures from the Singapore Cancer Society and Global Cancer Observatory www.ch.gov.hk
 ⁸ Journal of Clinical Oncology Abstract 2023 ASCO Annual Meeting 31 May 2023 https://ascopubs.org/doi/10.1200/JCO.2023

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

*Capturing the True Cost of Breast Cancer Treatment: Molecular Subtype and Stage-Specific per-Case Activity – Based Costing, 2023 Wilkinson AN, Seely JM, Rushton M, Williams P, Cordeiro E, Allard-Coutu A, Look Hong NJ, Moldeen N, Robinson J, Renaud J, Mainprize JG, Yaffe MJ. Capturing the True Cost of Breast Cancer Treatment: Molecular Subtype and Stage-Specific per-Case Activity-Based Costing, Curr Oncol, 2023 Aug

BREAST DENSITY'S IMPACT ON MAMMOGRAM ACCURACY

A mammogram is required to assess breast density

Breast density refers to white regions on a mammogram which contain fibroglandular tissue. Dense breasts can obscure cancer detection

Women with dense breasts are 4-5x more likely to develop breast cancer ¹

50% of women over 40 have dense breasts ²



UNMET NEED IN CURRENT BREAST IMAGING





Mammography sensitivity¹ drops from:

to

90%

64%

In **low density** breasts

In **high density** breasts

Millions of women face:

- Fear of missed cancers
- Unnecessary stress & procedures from false positives
- Significant healthcare costs without better imaging solutions



\$4bn_{pa}³

Collective cost of false-positive mammograms and breast cancer overdiagnoses to US healthcare

¹ Clinical Oncology Society of Australia (COSA). (2021). Mammographic / breast density: Facts and issues. COSA
 ² Kerlikowske et al., Annals of Internal Medicine, 2012
 ³ Health Affairs Vol. 34, No. 4: Cost & Quality Of Cancer Care 2015

THE CURRENT AUSTRALIAN SCREENING LANDSCAPE

1/200 women that screen have breast cancer...

Balancing cancer detection & unnecessary investigation is an ongoing challenge

21,000¹ New cancers per year

...yet up to 10% of women will undergo further investigation

<50yr Limited guidance or tools for screening, higher recall rates

~1.8M²

2D mammograms are performed each year without supplement ~50%

of women have dense breasts, yet no clear guidance on screening framework

National Breast Cancer Foundation (NBCF) BreastScreen Australia GE HealthCare

EXCITING FUTURE FOR R&D AT BCAL DIAGNOSTICS





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COMPANY OVERVIEW

ADVANCING BREAST CANCER SCREENING WITH A NON-INVASIVE BLOOD TEST

DEVELOPMENT PATH TO DATE





DETECTING LIPID SIGNATURES IN BREAST CANCER





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



BCAL has incorporated 15 years of knowledge and diagnostic technology to identify the presence or absence of breast cancer



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

A LIPID BLOOD TEST WITH AUTOMATED ANALYSIS

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



*This test has been validated and performed in a National Association of Testing Authorities (NATA) accredited laboratory. The test is currently under assessment by NATA for accreditation

BREASTEST $plus^{TM}$ **COMPLEMENTS** MAMMOGRAM



BREASTEST *plus*[™] IS DESIGNED TO COMPLEMENT BREAST IMAGING ALONGSIDE CLINICAL EXAMINATION, FAMILY HISTORY, MAMMOGRAM AND +/- ULTRASOUND

BREASTEST *plus*™ MARKET ROLLOUT



FOUR INITIAL KEY TARGET SEGMENTS



Phase 1 of BCAL launch;

- Working with existing screening partners in private health sectors
- Generate first revenues while continuing to build the databank
- ~ 50% of women have dense or extremely dense breast tissue¹;
- Younger women tend to have more dense breast tissue

1.5 million people who;

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

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

HIGHLY EXPERIENCED LEADERSHIP TEAM

WITH COMMERCIAL EXPERTISE TO DRIVE 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, advanced disease 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

An 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.

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



A/Prof. Cindy Mak

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



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 Samriti Sood

Breast Oncoplastic Surgeon



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



A/Prof. Gillian Lamoury

Radiation Oncologist and member of the Strategic Advisory Group for BCNA



A/Prof. James French

Head of Breast Surgery at the Westmead Breast Cancer Institute



Dr Sally Baron-Hay

Medical Oncologist specialising in Breast Cancer



Prof. Elisabeth Elder

Head of Research at the Westmead Breast Cancer Institute.



Prof. Mary Rickard OAM

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

WORKING WITH CLINICIANS FROM LEADING CENTRES AROUND THE GLOBE



BUILDING FOUNDATION FOR SUCCESS IN THE USA



¹ American Cancer Society <u>https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html</u>
² National Breast Cancer Foundation <u>https://nbcf.org.au/about-breast-cancer/breast-cancer-stats/</u>

SCIENTIFIC RESEARCH & BREASTEST *plusTM* DEVELOPMENT



- BREASTEST® technology has been developed over the last 15 years
- Discoveries have enabled the launch of BCAL's first product, BREASTEST plus^{™*}

- BREASTEST® will be a diagnostic product line for the detection and management of breast cancer
- R&D product pipeline includes:
 - Prospective clinical studies in AU, India and USA
 - Robust patent strategy to protect IP in major markets

*This test has been validated and performed in a National Association of Testing Authorities (NATA) accredited laboratory. The test is currently under assessment by NATA for accredited. This test is currently under assessment by NATA for accredited laboratory. The test is currently under assessment by NATA for accredited laboratory. The test is currently under assessment by NATA for accredited laboratory. The test is currently under assessment by NATA for accredited laboratory. The test is currently under assessment by NATA for accredited laboratory. The test is currently under assessment by NATA for accredited laboratory. The test is currently under assessment by NATA for accredited laboratory.

STRONG IP PORTFOLIO



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IN-LICENSED

BCAL DEVELOPED AND OWNED

Title	Jurisdiction	Status	Patent number	Expected expiry date	Title	Jı
Methods for detecting cancer*	AU	Granted	AU Pat. No. 2011270968	22 June 2031	Diagnostic signature	AU
Methods for detecting cancer*	AU (Div 1)	Granted	AU Pat. No. 2016213855	22 June 2031	Diagnostic signature	US
Methods related to cancer*	US (Div)	Pending	US 17/305,824	22 June 2031	Diagnostic signature	CA
Methods for detecting cancer*	CA	Pending	CA 2,803,865	22 June 2031	Diagnostic signature	CN
Methods for detecting cancer*	EP	Granted	EP Pat. No. EP 2585833	22 June 2031	Diagnostic signature	EU
Use of fatty acids in methods for detecting cancer*	EP (Div 1)	Granted	EP Pat. No. 3206034	22 June 2031	Diagnostic signature	JP
Methods for detecting cancer*	EP (Div 2)	Granted	EP Patent No. 3955004	22 June 2031	Diagnostic signature	PC
Methods for detecting cancer*	НК	Granted	HK Pat. No. 1180764	22 June 2031		
Methods for detecting cancer*	HK (Div 1)	Pending	HK 42022052007.6	22 June 2031	• 25 y	
Methods for detecting cancer*	JP	Granted	JP Patent No. 5944385	22 June 2031	• 9 µe	וו די
Methods for detecting cancer*	JP (Div 1)	Granted	JP Patent No. 6092302	22 June 2031	• 1 PC	
Methods for detecting cancer*	HK (Div 2)	Pending		22 June 2031		

Title	Jurisdiction	Status	Patent number	expiry date
Diagnostic signature	AU	Granted	2023258393	10 May 2043
Diagnostic signature	US	Filed	Pending	10 May 2043
Diagnostic signature	CA	Filed	Pending	10 May 2043
Diagnostic signature	CN	Filed	Pending	10 May 2043
Diagnostic signature	EU	Filed	Pending	10 May 2043
Diagnostic signature	JP	Filed	Pending	10 May 2043
Diagnostic signature	PCT stage	Filed	2023903491	31 Oct 2044

23 granted/accepted
9 pending
1 PCT stage family

RISING GLOBAL INCIDENCE DRIVING DIAGNOSTICS 2.3 MILLION NEW CASES ANNUALLY - 12% OF ALL NEW CANCER CASES



¹Breastcancer.org Breast cancer Facts and Statistics est. 2025 figures <u>https://www.breastcancer.org/facts-statistics</u> ² World Cancer Research Fund; est 2022 figures <u>https://www.wcrf.org/preventing-cancer/cancer-statistics/breast-cancer-statistics</u> ³ Current and future burden of breast cancer: Global statistics for 2020 and 2040; National Library of Medicine. <u>https://pmc.ncbi.nlm.nih.gov/articles/</u>

⁴ Breast Cancer Statistics, Breast Cancer Trials est. 2024 figures <a href="https://www.breast-cancer-resources/breast-cancer-resources

AL diagnostics

COMMERCIAL PATHWAY

A 3-YEAR ROADMAP TO IMPROVING OUTCOMES FOR WOMEN UNDERPINNED BY A REPRODUCIBLE LIPIDOMIC PLATFORM AND A PROPRIETARY BIOBANK OF GROWING DATA





Australian Launch & US Foundation

- Launch of BREASTEST *plus*[™] in March 2025 in AUS initially at Sydney Breast Clinic - NSW & VIC clinician sites to follow
- Accelerate awareness with Breast Surgeons, Breast Clinics, GP's, radiology and pathology providers, Breast care Nurses, Advocacy Groups, and Government agencies
- Develop and implement strategic partnerships to expedite market penetration
- Partner sites established in MI and IL collecting US samples
- Collaborate with US Physicians; Initiate relationship with US CLIAapproved lab

2 Scale Nationally

- Nationwide market access initiatives to take BREASTEST *plus*[™] across Australia
- Define and initiate market entry strategy for US commercial launch
- Expand patient sample processing capacity of Sydney lab
- Grow revenue with increased market access

03 Globalise

01

- Publish in scientific literature the clinical and utility performance of BREASTEST *plus*™
- Secure government funding for BREASTEST *plus*[™] in Australia
- Expand intended use and develop product line
- Consolidate and continue to grow volume in Australia

DELIVERING OUR STRATEGIC OBJECTIVES



	MAY 23	SEP 24	0CT 24	NOV 24	DEC 24	JAN 25	FEB 25	MAR 25	APR 25	MAY 25	JUN 25
Opened North Ryde, NSW Australia Laboratory											
Opened US operations including US Research Lab											
BCAL signs agreements to collect patient samples with two healthcare providers in USA											
Executed commercial agreement with Sydney Breast Clinic											
Collected more than 5000 samples in BCAL biobank for R&D											
BCAL research published in high profile, peer review journal											
Achieved NATA accreditation for North Ryde, NSW Laboratory											
Australia Patent Diagnostic Signatures granted											
Completed Australian clinical validation study											
Launch BREASTEST <i>plus</i> ™ & first revenues											

COMMERCIAL STRATEGY FY25/26



BREASTEST *plus*[™] SUPPLEMENTS MAMMOGRAPHY AS A RULE OUT TEST FOR BREAST CANCER

MILESTONE	Q1 2025 JAN - MAR	Q2 2025 APR - JUN	1H FY26 JUL - DEC	IMPACT
BREASTEST <i>plus</i> ™ launch at Sydney Breast Clinic		I		Initial market entry, real-world validation, and first revenues
BREASTEST <i>plus</i> ™ rollout – primary focus NSW & VIC				Expansion of market reach, brand awareness, and increased adoption among HCP
National AUS roll-out				Strengthened clinical credibility, enhanced trust in the product, and support for widespread adoption
Conference papers & publication in peer review journals				Increased visibility in the medical community, scientific validation, and potential partnerships
BREASTEST® Product 2			In FY26	Innovation to maintain competitive advantage and expand test applications
Research & continued development of BREASTEST® products for the US				Establishment of a strong foundation for global expansion and entry into the US market

INVESTMENT HIGHLIGHTS

- Breakthrough Blood Test Technology A first-in-class blood test* used in breast cancer detection as adjunct to mammogram
- BREASTEST plus [™] Launched In market at Sydney Breast Clinic available to eligible patients 18 and over, with a focused rollout in NSW & VIC to follow
- Scalable Market Opportunity Targeting a large addressable market with high unmet need, positioning for strong adoption and revenue growth
- Clinically Validated Performance Research on 351 prospectively collected blood samples demonstrated sensitivity of 0.91 and specificity of 0.49 (breast density D)
- Strategic Commercial Partnerships Established a licensing agreement with Sydney Breast Clinic, additional partnerships in discussion for broader distribution
- Global Expansion Strategy Secured laboratory infrastructure and clinical validation studies in progress in the US
- Proprietary Data & Al Advantage BCAL-owned blood biobank leverages Al-driven insights, differentiating from competitors by collecting and analysing proprietary sample datasets under stringent clinical protocols
- Strong IP Portfolio Multiple patents across key markets, including Australia, the USA, Europe, Canada, China, India, South Korea, and New Zealand; reinforcing competitive advantage
- Proven Leadership & Market Expertise Highly experienced team with a track record of successful product commercialisation, supported by a global Key Opinion Leader (KOL) network driving clinical adoption







BCAL diagnostics



Want To Learn More?

THANK YOU

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