



ASX Announcement

8 August 2023

BCAL Diagnostics Investor Education Update and Webinar

BCAL Diagnostics Limited (“BCAL” or “the Company”) (ASX: BDX) is pleased to attach an investor education update .

BCAL will host a webinar today, please see details below.

Investor Webinar Details

BCAL will be hosting an investor webinar on Tuesday 8 August 2023 at 11:00 am to update shareholders and provide further information on the Precion results and implications for the BCAL test.

The call will be hosted by Jayne Shaw, Executive Chair and Dr John Hurrell.

Webinar details Date:

Tuesday 8 August 2023

Time:

11:00am - 12:00pm (AEST)

To register:

[Register here](#)

Dial in details:

Will be provided to you upon registration

Participants will be able to submit questions during the webinar via a written Q&A facility displayed at the bottom of the webinar screen or can submit them in advance to bhall@bcaldiagnostics.com.

This announcement has been approved by the BCAL Board.

ENDS

Jayne Shaw

Executive Chair

jshaw@bcaldiagnostics.com

Guy Robertson

Chief Financial Officer

grobertson@bcaldiagnostics.com

About BCAL Diagnostics

BCAL Diagnostics Limited is an Australian screening and diagnostic company committed to the early, accurate diagnosis of breast cancer, and therefore early intervention and improved outcomes for women. Over the past decade BCAL has developed a non-invasive blood test for the detection of breast cancer. The test is initially designed to complement current imaging technologies, such as the mammogram, with the aim of becoming a monitoring and screening tool suitable for women of all ages and backgrounds in any location. With more than two million new cases of breast cancer diagnosed globally each year, a substantial opportunity exists for BCAL to improve patient outcomes. BCAL has partnered with Precion Inc. to optimise protocols and procedures for the clinical studies required for regulatory approvals across several jurisdictions, commercialisation and market entry points.

Founded in 2010, BCAL is headquartered in Sydney and listed on the Australian Securities Exchange (ASX: BDX). For more information: <https://www.bcaldiagnostics.com/>

About Precion Inc

Precision applies mass spectrometry technology to develop and provide targeted metabolite panels for profiling various chronic disease conditions and associated health areas for clinical research. Precision offers development of diagnostics and precision medicine assay formats for downstream applications. Precision's testing services for commercial and research customers provide data for various sample types and project objectives. Precision offers a range of targeted panels and custom developed panels for partners with specific clinical objectives. For more information: <https://www.precion.com/>

For persons

A revolution for breast cancer detection and management.

BCAL has developed and is commercialising a novel proprietary test to enable more effective detection and management of breast cancer.

Important notice and disclaimer



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The information in this Presentation is of a general background nature, is in summary form and does not purport to be complete. The information in this Presentation is subject to change without notice and, subject only to any legal obligation to do so, BCAL does not have any obligation to correct or update the contents of this Presentation.

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Company Metrics



ASX Code **BDX**

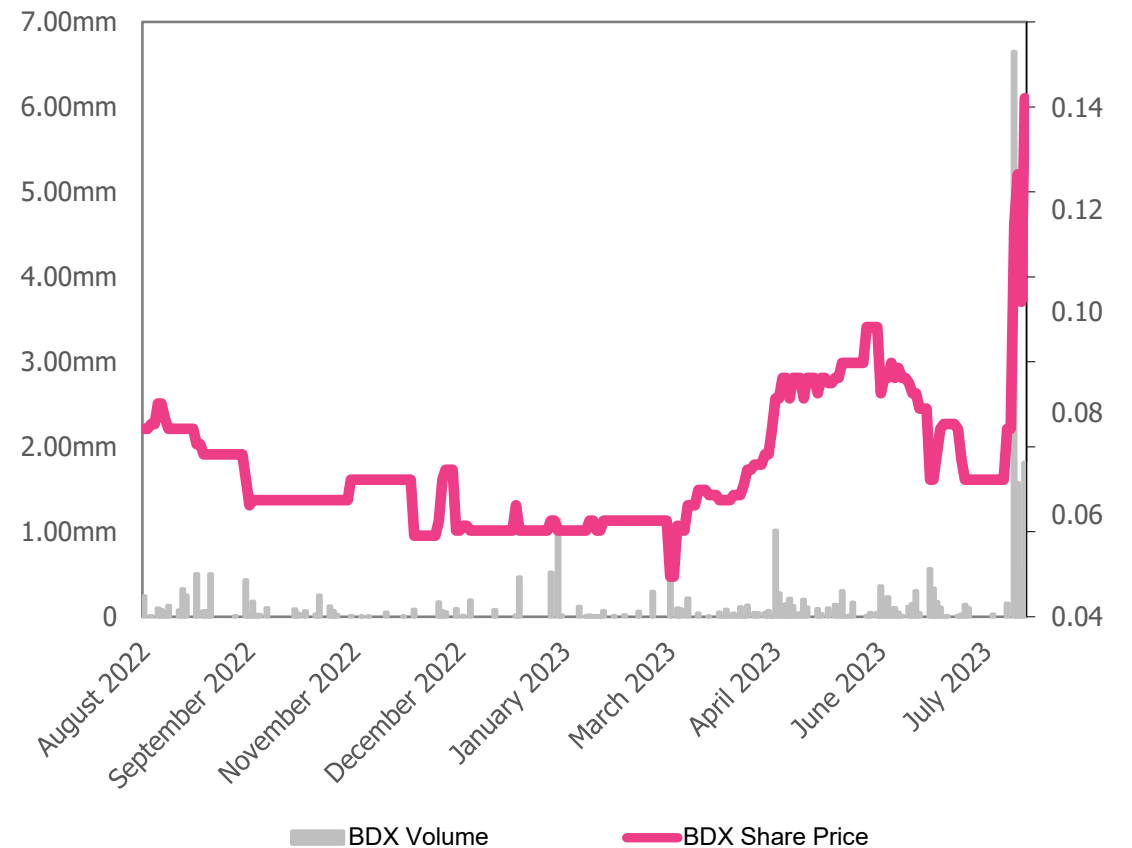
Share Price **\$0.145**
7 August 2023

Shares on Issue **211.4M**

Unlisted Options **11.5M**

Cash **\$3.2M**
30 June 2023

Top 20 Shareholders **66.6%**



To deliver global customers an effective, best-in-class, breast cancer detection and rule-out test, benefiting physicians and patients alike.

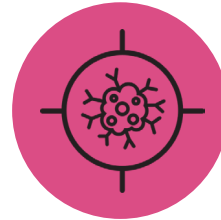
A paradigm shift for managing and caring for breast cancer.

ersonal use only

Executive Summary



BCAL is a cancer diagnostics company providing physician customers with proprietary detection and rule-out tests for breast cancer (BREASTEST™)



BREASTEST™ is uniquely positioned to address the unmet need for a more effective, patient friendly and accurate test for the early detection of breast cancer.



BREASTEST™ has shown consistent performance across the most common breast cancer sub-types.

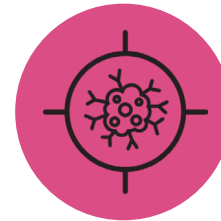
Recent results have confirmed accuracy and replicability of BREASTEST™ between laboratories in two different countries.



BCAL will begin to monetise its technology in 2024.

BREASTEST™ is on track to be launched with selected physicians in 2024.

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BCAL has recently received outstanding results from a clinical study it sponsored with Precion Inc.

The results show that BREASTEST™ can be replicated using standard equipment used in commercial laboratories throughout the world.



These results confirm the impressive sensitivity of 90% and specificity of 85.5% which are above the accuracy of mammography.

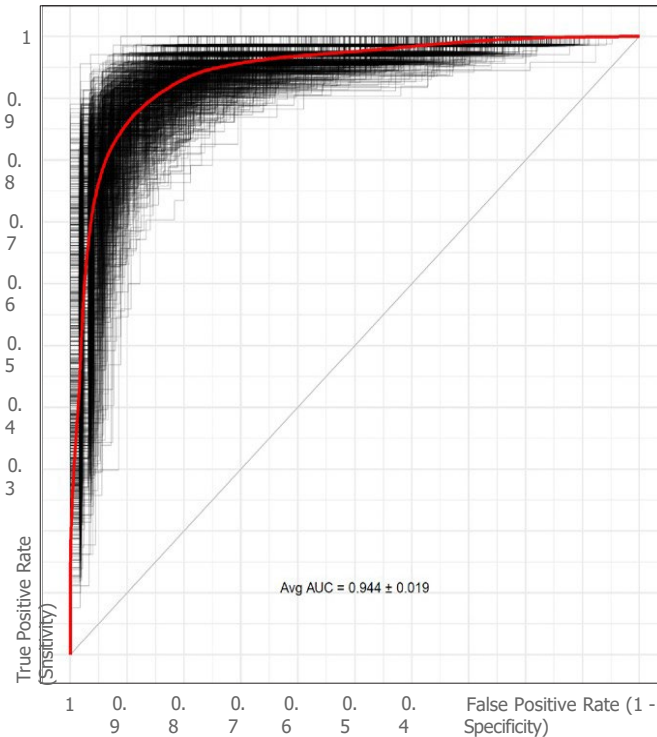


These results are a major breakthrough on the path to commercialisation and enhance the confidence of the Company that BREASTEST™ will be commercialised in late CY2024.

BCAL recently announced outstanding results from a clinical study confirming accuracy and demonstrating replicability of BREASTEST™.

BREASTEST™ outperforms mammography

Samples analysed by BCAL in Sydney on an OrbiTrap LC/MS Instrument



Sydney Study

353 Cancer patients
268 Negative patients

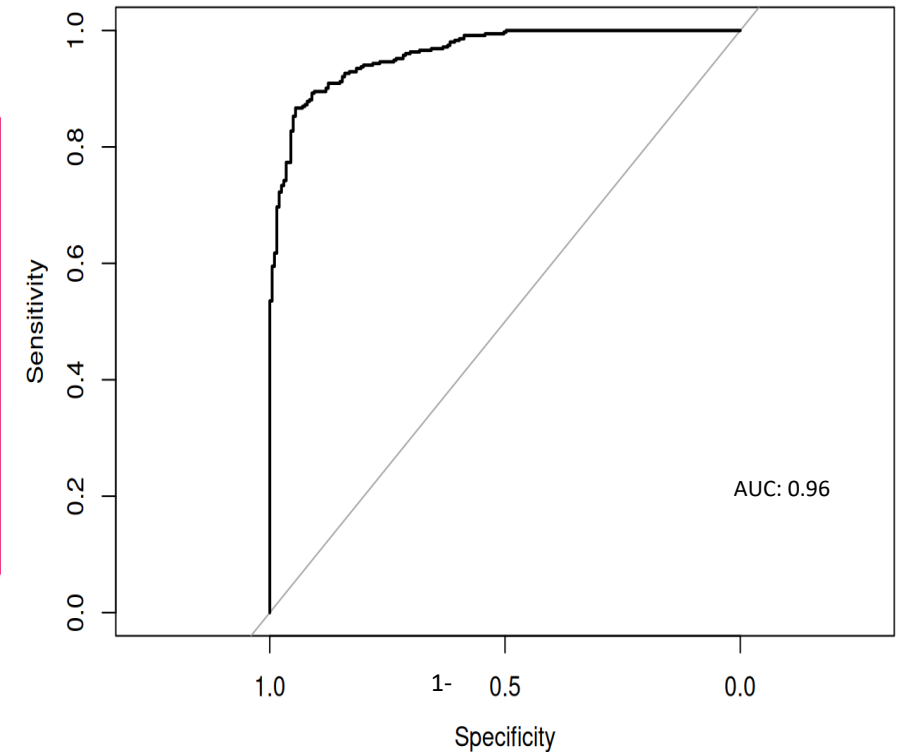
Accuracy: 88.0%
Sensitivity: 90.0%
Specificity: 85.5%

20 Lipid Signature
Analysis via Machine Learning

Unpublished internal case-control study of European and Australian patients

BCAL DIAGNOSTICS LIMITED

Samples analysed by Precion in USA on a Triple Quad LC/MS Instrument



Precision Study

390 Cancer patients
266 Negative patients

Accuracy: 88.0%
Sensitivity: 90.9%
Specificity: 85.5%

24 Lipid Signature
Analysis via Machine Learning

The compelling global opportunity that we address



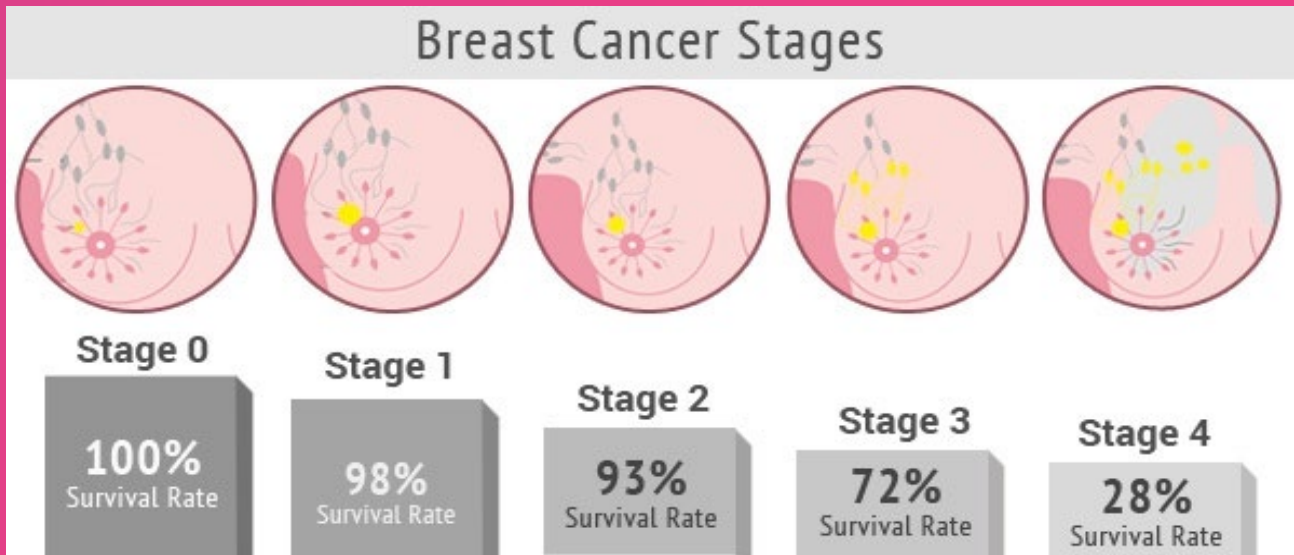
1 in 7 women in Australia will receive a breast cancer diagnosis during their lifetime.

Breast cancer is the most common cancer in women in the US after skin cancer.

Breast cancer is the second leading cause of cancer death in the US after lung cancer.

1 in 39 women currently die from breast cancer
Source: Cancer.org.

Early diagnosis is key to increased survival rates



Limitations of mammography



Not definitive

20% of breast cancers are missed - false negatives.

Limited accuracy

prone to false positives.

Guidelines limit access to over 40 y/o only

Prone to self-exclusion

painful, uncomfortable, cultural reasons.

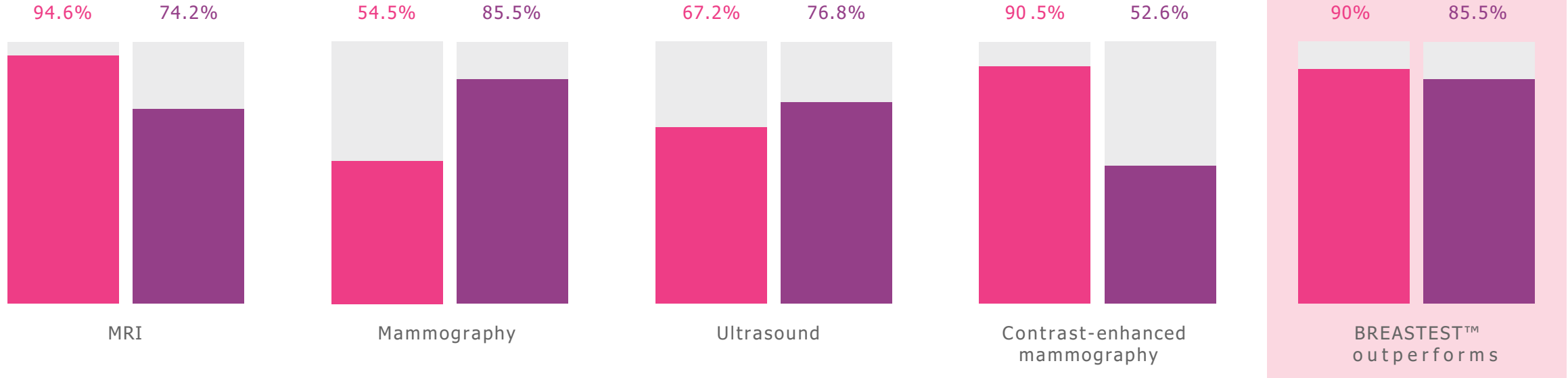
Most effective above 50 y/o due to breast density and fatty tissue

Limited remote access

BREASTEST™ outperforms existing standards of care



There is currently no completely effective detection or rule out test available for breast cancer



A cancer detection test requires a balance of sensitivity (ability to detect true positive samples) and specificity (ability to detect true negative samples).

- SENSITIVITY
- SPECIFICITY

Internal validation of BREASTEST™ shows strong potential performance with a balance between sensitivity and specificity.

Personal use only

An effective and accurate blood test should increase the screening detection rate and reduce mortality

Dr Gillian Lamoury, Radiation Oncologist, Sydney, in a paper presented at ASCO 2023: Lipidomic signature from plasma to detect localised breast cancer



Commercialisation of BREASTEST™ on track for 2HCY24



14 years of development

BCAL commenced operating in 2009.

Over 2,000 independent patient and control samples tested

Demonstrating consistent and robust level of accuracy.

IPO in 2021 raised funds to accelerate development

BCAL has met prospectus forecasts in developing BREASTEST™.

Uses liquid chromatography-mass spectrometry

BCAL is at the cutting edge of use of lipidomics for cancer diagnostics.

BCAL has assembled a leading scientific and management team.

BREASTEST™ has been developed in close collaboration with clinicians and scientists globally.

Building a pipeline of tests for other cancers with our proprietary lipidomic platform.

State-of-the-art commercial laboratory commissioned and operating.

BREASTEST™ holds strong and growing Intellectual Property Protection.

Initial roll out planned for 2HCY24 in Australia, followed by US, Europe and broader APAC.

Board of Directors



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.



Jonathan Trollip
Independent Non-executive Director

International businessman and lawyer. Many years of experience as NED of large ASX-listed companies.



Dr. Merilyn Sleigh
Independent Non-executive Director

Over 30 years' experience as a senior executive and non-executive director in Australia's biotechnology sector and academia.



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.

Executive Team - Australia



Dr. John Hurrell, PhD
Chief Executive Officer

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. 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
Regulatory and Quality Manager

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.



Amanda Koegelenberg
M.BioTech. M. Comm.
Director, Clinical Affairs

Former Associate Director of Research, Research Program Director for NSW Health Pathology. Extensive experience in Biobank development and clinical research. Has managed multisite clinical studies including sites outside Australia.



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.

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Key People - USA



Dr. John Hurrell, PhD
Chief Executive Officer

More than 35 years' experience in life sciences & healthcare. Has developed & successfully commercialised multiple products & services and managed start up/early-stage companies.



Dr. Kim Ekroos, PhD
Scientific Advisor

Founder and CEO of Lipidomics Consulting Ltd., a global consulting business in the field of Lipidomics with over 20 years' experience.



Dr. David Peake, PhD
Scientific Lead, Technology Transfer

Expert in Lipidomics and mass spectrometry. Expertise with both qualitative and quantitative methods



Dr. Raji Pillai, PhD
Regulatory Consultant

Expertise in developing innovative molecular diagnostics under FDA and CLIA regulations, and fielding effective interactions with regulatory agencies.



David Darling
Consultant

EX CEO of Pacific Edge, a NZX50 business focused on commercialising its bladder cancer diagnostics tests in global markets. David has a background as a scientist, with a speciality in genetics.

Clinical and Scientific advisors - Australia



A/Prof. Craig Gedye
BSc(Hons), MBChB, FRACP, PhD

A medical oncologist and cancer researcher at the Calvary Mater Newcastle, and is the Clinical Research Director at the NSW Health Statewide Biobank.



Dr. Sanjay Warriar
(Associate Prof.) BSc (Med) MBBS
FRACS MS

Consultant Breast Oncology and Oncoplastic Surgeon at Chris O'Brien Lifehouse, Royal Prince Alfred and Mater Hospitals. He is also a Visiting Medical Officer at BreastScreen NSW.



Dr. Gillian Lamoury
BMed FRANZCR, Radiation Oncologist

Gillian is a dedicated radiation oncologist with clinical interests in breast cancer, sarcoma, and lymphoma.

Gillian is a dynamic and thoughtful clinician who is passionate about offering personalised patient care. She collaborates with her patients to build individualised care plans that integrate evidence-based treatment and modern techniques.

Gillian is a dedicated teacher and lecturer of medical students at the Northern Clinical School, and she is a conjoint senior lecturer with the University of Sydney.



Prof. Dr. Mary Rickard AO

A leading expert in mammography. Involved in consulting with numerous breast screening and diagnostic training programs across South East Asia.



Prof. Peter Meikle, PhD
Baker Institute

NHMRC Senior Research Fellow Leads the Obesity and Diabetes Program and is Head of the Metabolomics laboratory.

The greatest challenges in detecting and managing breast cancer in young women are:

1. There are no effective breast screening options available for young women.
2. There is no complementary technology OR education alternatives for breast screening or testing for young women.

Therefore, the probability of detecting and appropriately managing breast cancer in young women is poor.

Rachelle Panitz, diagnosed with breast cancer aged 32

Founder of the young breast cancer patient advocacy group SoBrave, sobrave.org.au

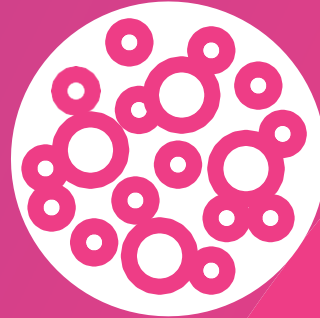
Intended use at launch: BREASTEST™ will have a significant impact on these high-risk patients



Patients with abnormal mammograms requiring further investigation.

In 2021, a total of 192,529 women in Australia over the age of 50 had an abnormal mammogram.

(Breast Screen Australia 2022 Report)



High risk dense breast population.

Half of women aged below 50 have “dense or very dense breasts”. Breast density makes the interpretation of mammograms more difficult, while the incidence of cancer in women increases with the level of density of their breasts.

Correlation between dense breasts and risk of cancer.

In 2021, there were 1,671,420 women in Australia between 40 and 50 years-old.

(Australian Bureau of Statistics Report 2022)



Patients with known genetic risk of breast cancer.

BREASTEST™ could allow more frequent testing without the additional exposure to radiation or the cost and access difficulty of an MRI. There are about 10,000 women in Australia with a mutation in their BRCA genes which puts them at high risk.

Long term intended use objectives

BREASTEST™ targeting large and diverse groups of at-risk patients

ersonal use only

1

Patients who do not currently get screened.

2

Patients with abnormal mammography findings. It is estimated that up to 90% of patients with initial abnormal mammography findings are ultimately classified as negative for breast cancer.

3

High risk patients requiring more intense monitoring or diagnosis.

4

Presence of cancer after treatment. There currently are no diagnostic offerings to determine if a patient is cancer-free after treatment.

5

Monitoring for recurrence of disease.

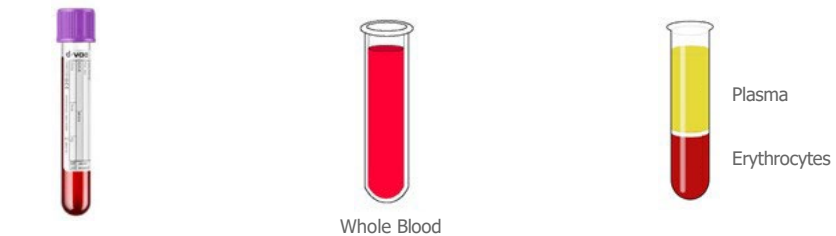


BCAL's state-of-the-art lipid test BREASTEST™ with automated analysis



BREASTEST™

At collection centre



Blood collection

Whole Blood

Plasma
Erythrocytes

Pre-processing: sample spin, separate and freeze

Transit

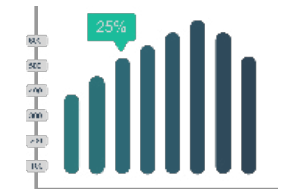


Sample preparation: plasma lipid extraction

At testing laboratory



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



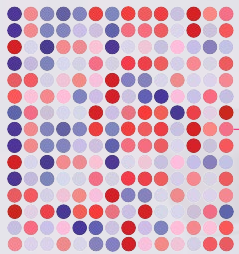
Data analysis for breast cancer lipid signatures (presence or absence)

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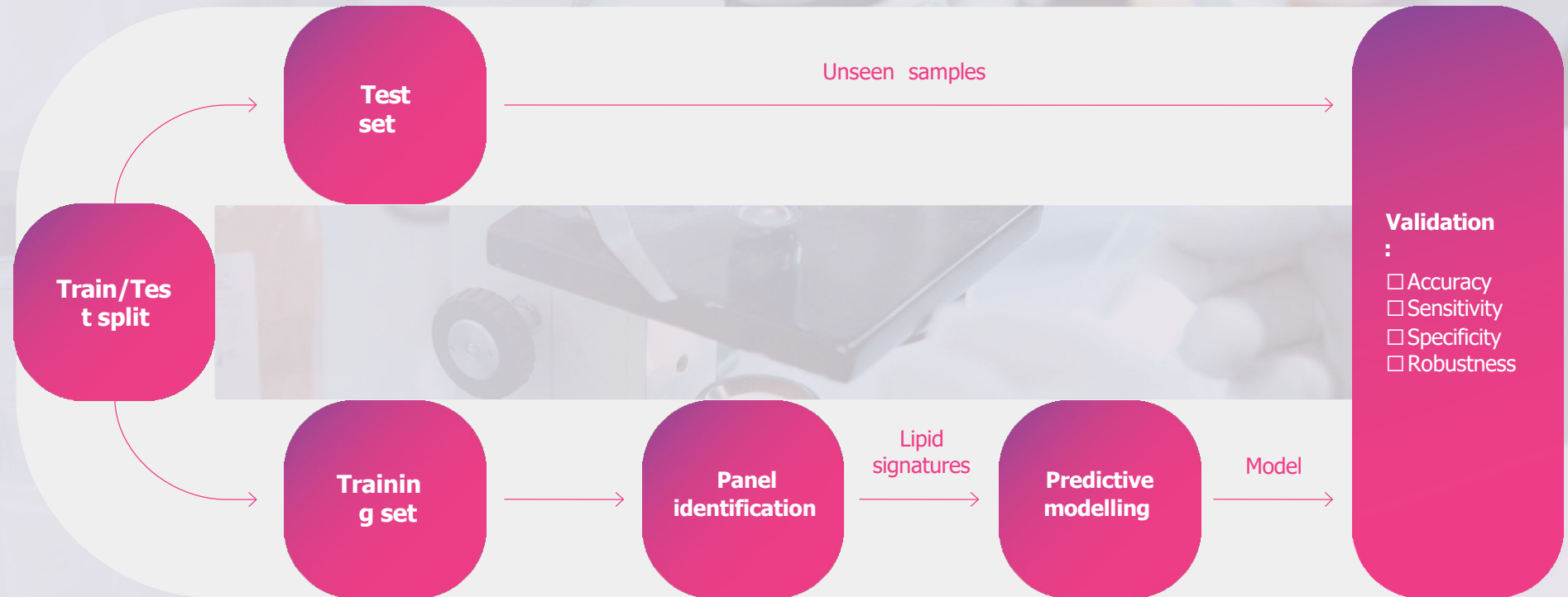
Discovery pipeline: using AI/machine learning techniques to develop diagnostic algorithms

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Lipids or Variables



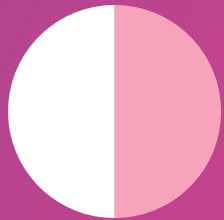
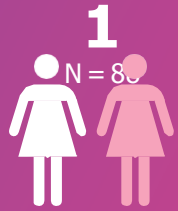
Samples



BCAL's clinical evidence development for key breast cancer types

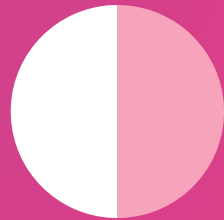
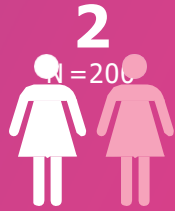


Cohort 1



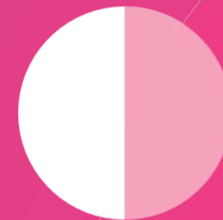
IDC
(Stages 1-4)

Cohort 2



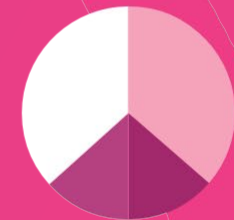
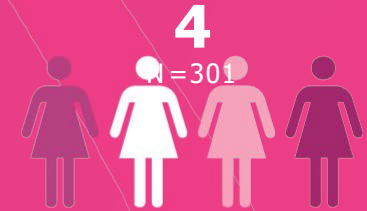
IDC
(Stages 1-2)

Cohort 3



IDC
(Stages 1-2)

Cohort 4



DCIS (Stages 0)
IDC (Late Stages)
ILC (Early Stages)

● Control ● IDC ● DCIS ● ILC

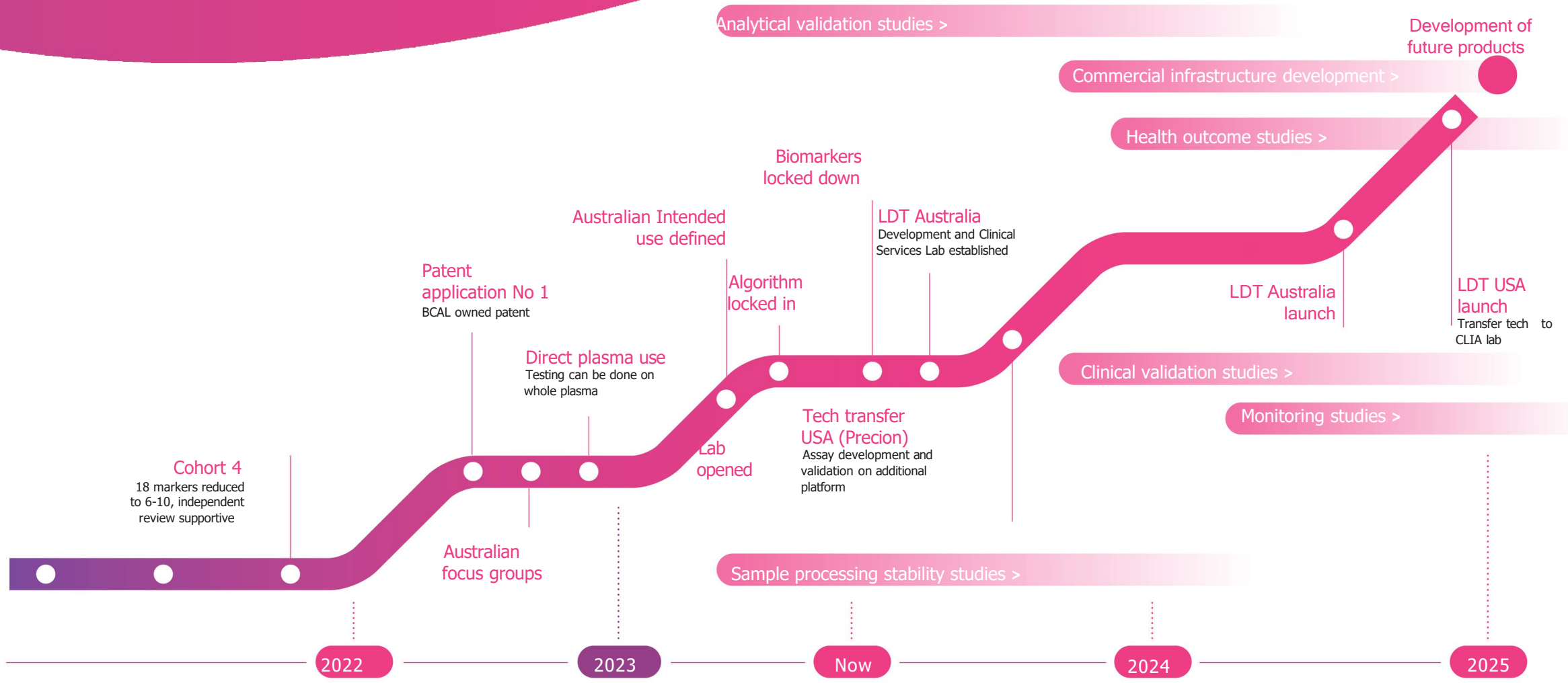
IDC: Invasive Ductal Carcinoma

DCIS: Ductal Carcinoma in Situ

ILC: Infiltrative Lobular Carcinoma

Journey to commercial launch and revenue

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Commercial market launch in Australia is on-track for 2024



BREASTEST™ commercialisation pathway will include Medicare reimbursement in Australia (we expect soon after launch), out-of-pocket payment in New Zealand. The USA is Medicare (USA) for all patients over 65 years, private payer insurance for those not insured or covered.

Retail price for Australia and New Zealand is currently expected to be around AUD\$350.

BREASTEST™ has strong and growing Intellectual Property Protection



Status	Country	Application Title	Filing Date	Patent Number
Issued*	Australia	Methods for Detecting Cancer	Jan 7, 2013	AU Pat. No. 2011270968
	Australia	Methods for Detecting Cancer	Aug 12, 2016	AU Pat. No. 2016213855
	Japan	Methods for Detecting Cancer	Dec 20, 2012	JP Patent No. 5944385
	Japan	Methods for Detecting Cancer	May 29, 2015	JP Patent No. 6092302
	Europe FR,NL,GB,IT,DE,ES	Methods for Detecting Cancer	Jan 23, 2013	EP Pat. No. EP 2585833
	Europe FR,NL,GB,IT,DE,ES	Methods for Detecting Cancer	Mar 27, 2017	EP Pat. No. EP 3206034
	Hong Kong	Methods for Detecting Cancer	Jul 5, 2103	HK Pat. No. 1180764

Status	Country	Application Title	Filing Date	Application Number
Pending*	Canada	Methods for Detecting Cancer	Dec 21, 2012	CA 2,803,865
	US	Methods for Detecting Cancer	Jul 15, 2021	US 17/305,824
	Europe	Methods for Detecting Cancer	Sep 29, 2021	EP 21200018.6
	Hong Kong	Methods for Detecting Cancer	Apr 20, 2022	HK 42022052007.6

In Progress	Australia	Diagnostic Signature	May 10, 2022	APPA 2022901245
	Australia	Diagnostic Signature		In preparation

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Thank You

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