

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.

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Company Metrics



ASX Code

BDX

Share Price

23 August 2023

\$0.115

Shares on Issue

Pre-Offer

213.2M

Unlisted Options

9.2M

Performance Rights

8.3M

Cash

30 June 2023

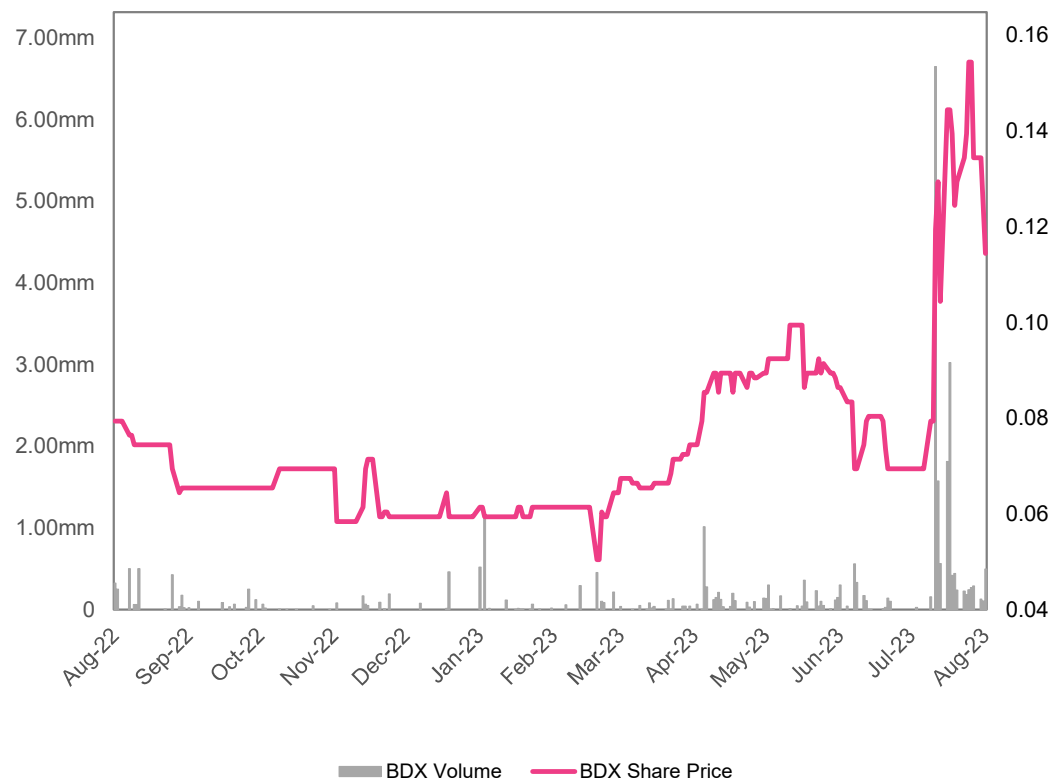
\$3.2M*

Top 20 Shareholders

66.6%

*Excludes ~\$2.5m R&D taxation rebate for FY23

BCAL DIAGNOSTICS LIMITED

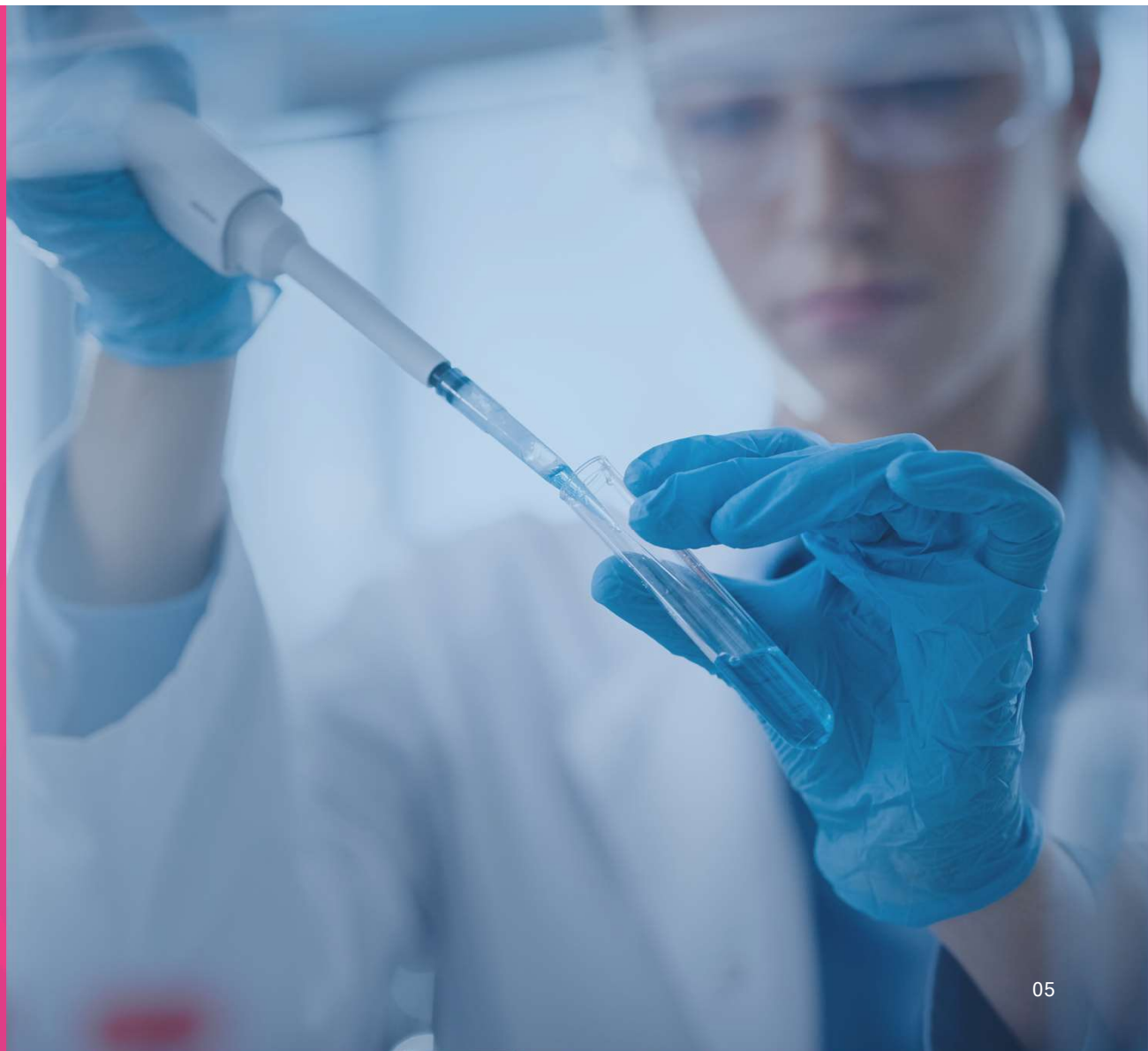


To deliver global customers an effective, best-in-class, breast cancer detection and rule-out test, benefiting physicians and patients alike.

A paradigm shift for managing and caring for breast cancer.

Executive Summary

BCAL DIAGNOSTICS LIMITED



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



BCAL DIAGNOSTICS LIMITED



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.



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

BCAL DIAGNOSTICS LIMITED



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.

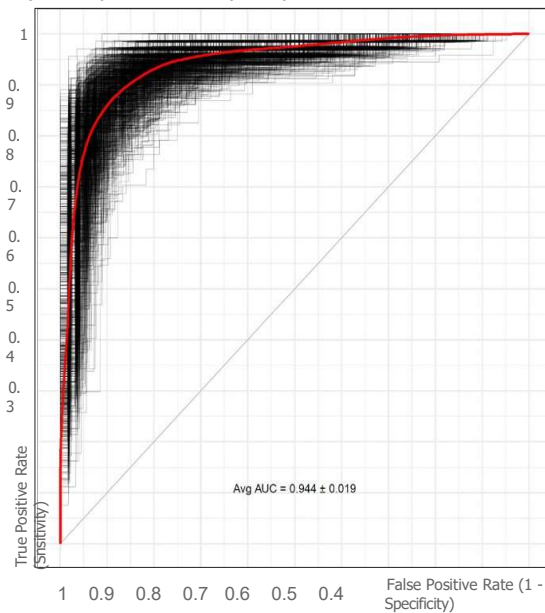
BREASTEST™ outperforms mammography

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

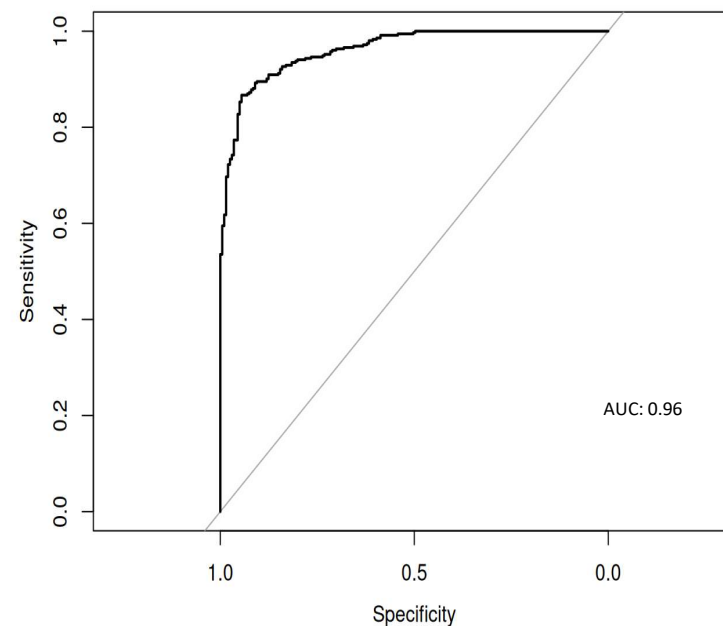
BCAL DIAGNOSTICS LIMITED

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.

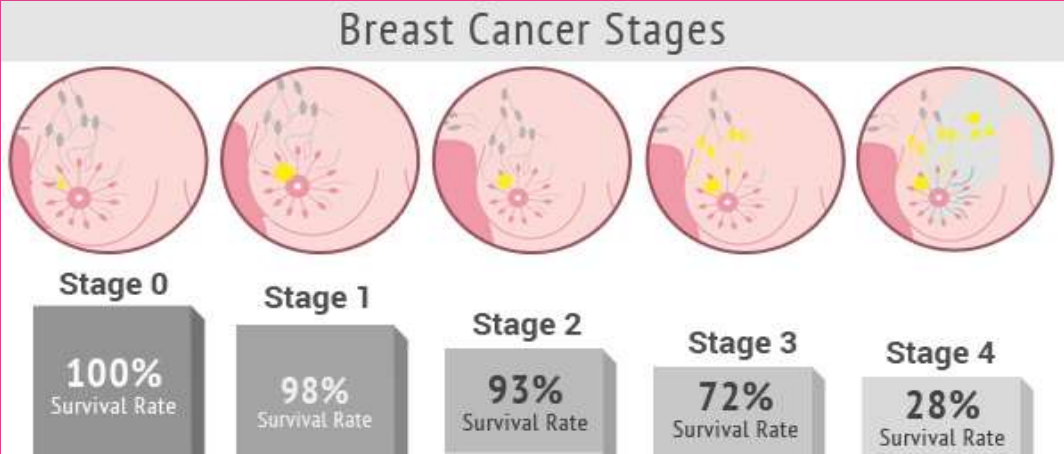


Breast cancer is the second leading cause of cancer death
in the US after lung cancer.

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

Early diagnosis is key to increased
survival rates

BCAL DIAGNOSTICS LIMITED



<https://www.pinkribbon.org.pk/stages-breast-cancer/>

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.

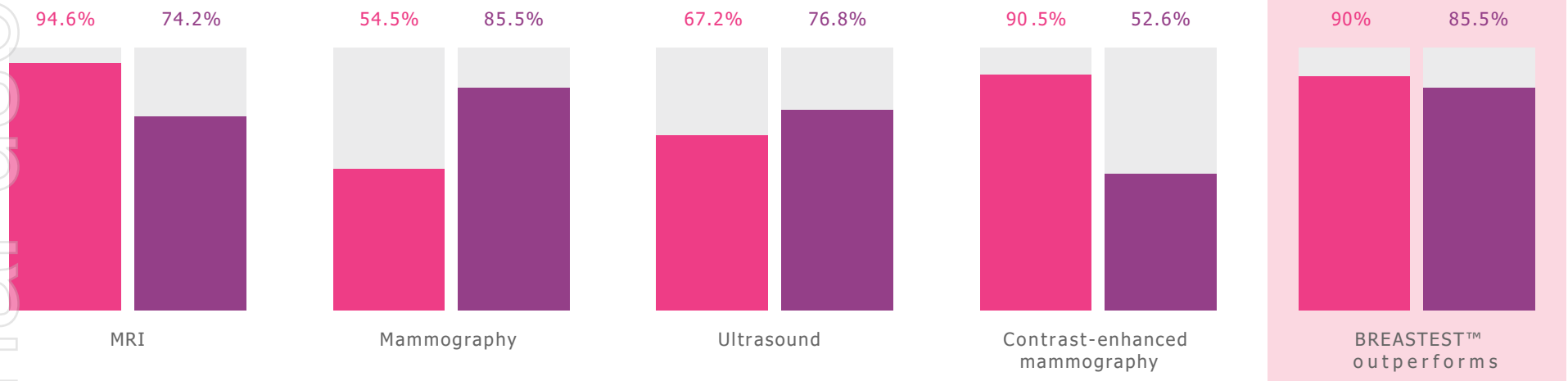
Most effective above 50 y/o due to breast density and fatty tissue

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.

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.

IPO in 2021 raised funds to accelerate development

BCAL has met prospectus forecasts in developing BREASTEST™.

Over 2,000 independent patient and control samples tested

Demonstrating consistent and robust level of accuracy.

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.

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

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

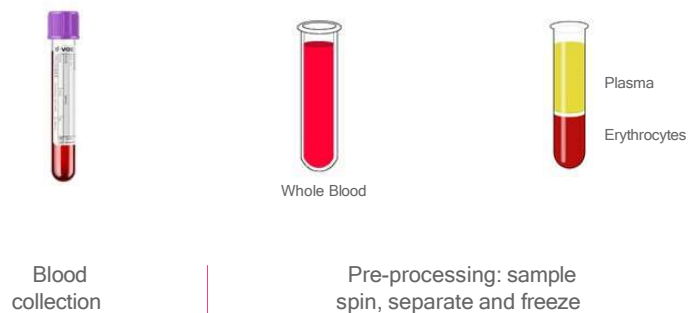
Monitoring for recurrence of disease.

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



BREASTEST™

At collection centre



Transit



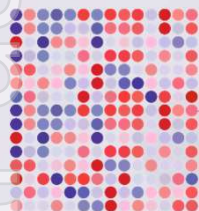
At testing laboratory



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



Lipids or
Variables



Samples

Train/Test
split

Test set

Unseen samples

Training
set

Panel
identification

Lipid
signatures

Predictive
modelling

Model

Validation:

- ☐ Accuracy
- ☐ Sensitivity
- ☐ Specificity
- ☐ Robustness

BCAL's clinical evidence development for key breast cancer types

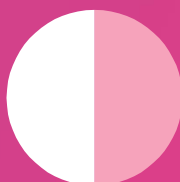


Cohort 1
N=88



IDC
(Stages 1-4)

Cohort 2
N=200



IDC
(Stages 1-2)

Cohort 3
N=201



IDC
(Stages 1-2)

Cohort 4
N=301



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

Legal statement



BCAL intends to commercialise the Test and supply it as an in-house test once its laboratory has been accredited by the National Association of Testing Authorities (**NATA**) to perform the Test. NATA is the recognised national accreditation authority for analytical laboratories and testing service providers in Australia, and is responsible for accrediting laboratories that develop/manufacture *In Vitro* Diagnostics (IVDs) in-house (*i.e.* IVDs that are developed and supplied within a laboratory and are not supplied outside the laboratory).

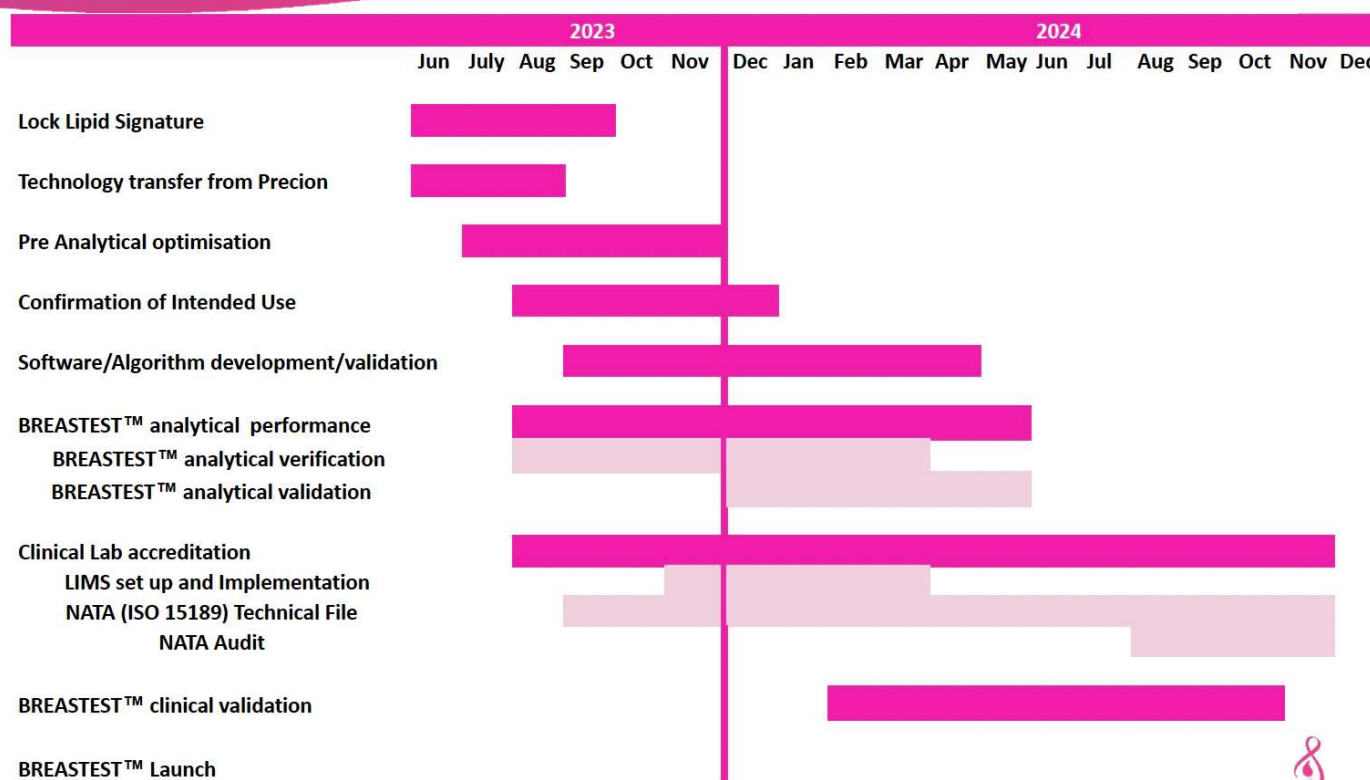
Inclusion in the Australian Register of Therapeutic Goods (**ARTG**) is not required for Class I to 3 IVDs that have been developed in-house in a laboratory that has obtained NATA accreditation for the IVD. However, the laboratory must comply with the conformity assessment procedure prescribed under the *Therapeutic Goods (Medical Device) Regulations 2002*, which requires that the laboratory be accredited by NATA as a medical testing laboratory that complies with ISO 15189 standards and with the National Pathology Accreditation Advisory Council (**NPAAC**) standard titled *Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices*.

BCAL's ongoing development includes generating the analytical data required to validate the Test, and other data required to demonstrate that its laboratory complies with ISO 15189 and the NPAAC standard. BCAL is working towards obtaining accreditation of the laboratory and Test by mid fourth quarter of CY2024.

Once NATA accreditation has been obtained, BCAL will be able to make the Test commercially available, supplied within its laboratory and generating revenue for the business for the first time. This milestone will complete the first phase of BCAL's commercialisation strategy.

Dr Teresa Nicoletti | Partner - Mills Oakley

Journey to commercial launch and revenue



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
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

* Licensed exclusively from the University of Louisville

The Offer

BCAL DIAGNOSTICS LIMITED



Investment Opportunity

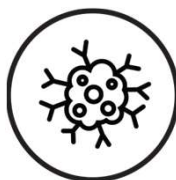


AU\$
2.5
million
equity investment

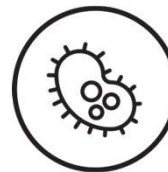
Raising AU\$2.5 million for product development and to launch BREASTEST™ initially in Australia and New Zealand

Physicians and cancer patients are highly-motivated to find detection and rule-out tests for small breast tumours and to create tests that provides simple and easy blood **draws**.

Funds will enable the science validation, development and publication of the clinical evidence to support the launch of BREASTEST™ with selected physician customers. Extend the IP protection and commercial partnering with selected physician customers globally.



Internal validation of the test algorithm on the commercial platforms and lock-down the commercial protocols.



BREASTEST™ Launch of BREASTEST™ with selected physician partners in Australia and New Zealand providing commercial validation.



Agreements with Healthcare providers in Australia and New Zealand.



Further extend patenting and IP protection
Including valuable platform data.

Capital Raising Structure



Offer size and structure	<p>Placement to sophisticated and professional investors to raise gross proceeds of approximately \$2.0 million of new ordinary shares ("New Shares") under the company's existing placement capacity per LR 7.1 & 7.1A ("Placement").</p> <p>In conjunction with the Placement, the Company is conducting a Share Purchase Plan ("SPP") seeking to raise up to \$0.5 million (together the Placement and SPP being the "Capital Raising"). The SPP will be offered at the same Offer Price as the Placement and will enable existing eligible shareholders to apply for up to \$30,000 worth of Securities.</p>
Offer Price	<p>New share under the Capital Raising will be issued at a price of \$0.10 per New Share representing a:</p> <ul style="list-style-type: none"> • 13.04% discount to the last traded price on Wednesday 23rd August 2023 A\$0.115 per share. • 24.99% discount to 5-day VWAP of \$0.1333¹. • 29.36% discount to the 15-day VWAP of \$0.1416¹.
Ranking	<p>The New Shares subject to the Capital Raising are fully paid shares in BCAL and will rank pari passu with existing fully paid ordinary shares from allotment.</p>
Use of Funds	<ul style="list-style-type: none"> • Clinical studies to define the intended use with the help of an international contract research organisation. • Building out the clinical services laboratory with equipment and staff and gain compliance with NATA certification of ISO15189 and NPAAC. (National Pathology Accreditation Advisory Council). • Building the commercial organisation and expanding the pipeline of tests to other cancers, particularly ovarian, lung, prostate, and brain cancer. • Further build out clinical evidence (through to having a reimbursable product). • License BCAL's product to targeted healthcare providers and physicians. • General working capital
Joint Lead Managers	<p>MST Financial Services Pty Ltd ("MST") & PAC Partners Securities Pty Ltd ("PAC") acted as Joint Lead Managers to the Offer</p>

Indicative Timetable



Summary of Key Dates	Date
Trading Halt and Placement bookbuild	Thursday, 24 August 2023
SPP Record Date	Friday, 25 August 2023
Company Announcement & Trading Halt lifted	Monday, 28 August 2023
Despatch of SPP offer booklet & SPP opens	Wednesday, 30 August 2023
Settlement of New Shares under the Placement	Thursday, 31 August 2023
Allotment of New Shares under the Placement	Friday, 1 September 2023
SPP offer Closes (5.00pm AEST)	Wednesday, 13 September 2023
Issue of SPP securities	Monday, 18 September 2023
Quotation of SPP securities	Tuesday, 19 September 2023

The dates and times are indicative only and subject to change by the Company's in consultation with the Joint Lead Mangers

Key Risks



This section contains some key risks associated with an investment in the Company. BCAL's business is subject to several risk factors, both specific to its business and of a general nature which may impact on its future performance and forecasts.

This is not an exhaustive list of relevant risks, and the risks below are not in order of importance. Many of them are outside the control of BCAL and its directors. These risks and other risks may in the future materially adversely affect the value of BCAL's shares and their performance. Accordingly, no assurance or guarantee of future performance or profitability is given by BCAL in respect of the Company's shares.

Before subscribing for BCAL's shares, prospective investors should carefully evaluate BCAL and its business and consider their own investment objectives and financial circumstances and material risk factors including those below.

In deciding whether to participate in the Capital Raising, prospective investors should carefully consider including the risks outlined in this section. Prospective investors should also consider publicly available information on BCAL, including on its website www.bcaldiagnostics.com, and consult their financial, tax and other professional advisers before making an investment decision.

Sufficiency of funding	BCAL may need to raise additional funding from time to time to finance its operations. The Company gives no assurance that future funds can be raised on favourable terms, if at all. If BCAL cannot raise future funding as and when desired this will adversely impact its ability to achieve milestones and develop its product.
Competition	The Company has competitors that may have significantly greater financial, technical, human, research and development and marketing resources than the Company. Consequently, the Company's proposed products and technologies may become obsolete or uncompetitive.
Reliance on key personnel	The Company currently employs a number of key management and scientific personnel, and the Company's future depends on retaining and attracting suitably qualified personnel. While certain measures have been taken in relation to recruitment, retention and contracting to secure its key personnel, there is no guarantee that the Company will be able to attract and retain suitably qualified personnel. Such a failure could materially affect the business, operating results and financial prospects of the Company.
Legislative risk	There is a risk that in Australia, the US and other jurisdictions the legislative regime governing LTD (Laboratory Developed Tests) may change. These changes may impact the Company's proposed development of an LTD for BREASTEST™ and the development of other products.

Key Risks (continued)



No regulatory approval	The intended use of BREASTTEST™ as a diagnostic tool in Australia requires approval from the TGA as a Class III device for an IVD. The company is working closely with expert professional lawyers and taking all measures it can to maximise the chances of obtaining this approval from the TGG but there is no assurance as to if and when it will be forthcoming.
Test reimbursement	The Company's financial future financial performance is going to be impacted by the extent to which BREASTTEST™ and any other tests developed by the Company are eligible for reimbursement from governments, health insurers and healthcare organisations. While the Company considers there are good grounds why reimbursement should be available in due course, no assurance can be given.
Lack of samples	The Company's long-term performance is going to be dependent upon accessing and testing blood samples from a diverse patient population. No assurance can be given that the Company will be able to obtain the samples on a cost-effective basis if at all.
Operational issues	The Company's laboratory uses sophisticated technical equipment in running its sample analyses and for other purposes. Equipment failures and delays may therefore impact negatively on the Company's operations.
Intellectual property	The Company is reliant upon licenses and patents and trademarks to protect the intellectual property it has and is developing. There is a risk that competitors may seek to appropriate the Company's intellectual property. This would impact adversely on the Company's business including the risk inherent in taking legal action to enforce intellectual property rights.
Share market investment risk	An investment in the Company shares encompasses the usual risks associated with share investment in listed companies. These include general equity market risk, currency risk, liquidity risk, interest rate risk, economic risk, tax risk and change of law risk.

Thank You

info@bcaldiagnostics.com

t +61 (0) 407 983 270

Suite 506, Lvl 5, 50 Clarence Street,
Sydney NSW 2000

www.bcaldiagnostics.com