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DRIVING A NEW PARADIGM IN BREAST CANCER
DIAGNOSTICS



Shareholder Update Laboratory Tour

15th October 2024

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COMPANY METRICS



ASX Code

BDX

Share Price

14 October 2024

\$0.14

Shares on Issue

358.6M

Unlisted Options

4.5M

Cash

15 October 2024

\$6.5M (+\$2.5M R&D rebate)

Top 20 Shareholders

52%

A LIPID BLOOD TEST WITH AUTOMATED ANALYSIS

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

BREASTEST®

AT COLLECTION CENTRE



Blood collection



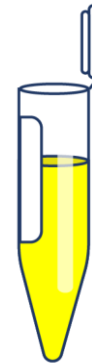
Whole Blood



Plasma
Erythrocytes

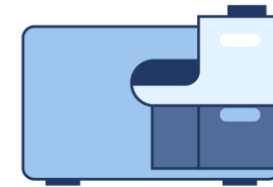
Pre-processing: sample spin, separate and freeze

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

BCAL HISTORY

2013-2017

"Proof of concept" studies with North American and Australian partners to confirm that the lipids of interest were contained in cell signals

Proof of concept studies

2010-2013

Completed *invitro studies* that identified alterations in certain lipids from breast cancer cells

In vitro studies

2017-2021

Completed studies whose results showed accurate identification of cancer especially in early stages, independent of age, with 91% sensitivity and 87% accuracy in some cohorts using 18 candidate lipid markers

Cohort testing

2021-2024

Australian clinical studies

Australian clinical studies

2022-2023

Breakthrough results (Aug '23) from Precion study

Precision studies

2010

Founded as SBC Research (born from Sydney Breast Clinic) to develop a novel and universal breast cancer-screening test

2014

Changed name to BCAL diagnostics

2015

2016

2017

Established research operations at the Charles Perkins Centre – at the University of Sydney

2018

2019

2020

Ethical approval granted for Stage 1 clinical trial at Sydney hospitals and breast cancer clinics

2021

2022

Locks down crucial breast cancer signature + Opens development and clinical service laboratory

2023

US laboratory commences operations + Commercial licence agreement with SBC

2024



RECENT PROGRESS

Publications

- First manuscript submitted for publication in a peer reviewed International Journal. Very positive feedback so far on the content of the paper
- Identification of Plasma Lipid Biomarker Distinguishing Breast cancer Patient from Health Controls
- Second manuscript now in draft
- IP portfolio continues to strengthen and is an ongoing focus

NATA accreditation

- Full day assessment conducted 30 September
- The assessors very impressed by the laboratory, the team and the quality of our systems. We await the outcome

Sample Collection

- Endeavour Health Chicago commencing recruitment very soon
- Clinical Validation Study 75% recruited
- Collection of other tumour stream samples under BCAL protocol

Commercial

- SBC agreement completed and will be our first launch site. Announced recently
- Additional private, multidisciplinary sites for rollout across Victoria and NSW identified and discussions are in progress
- Appointment of National Clinical Program Director

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

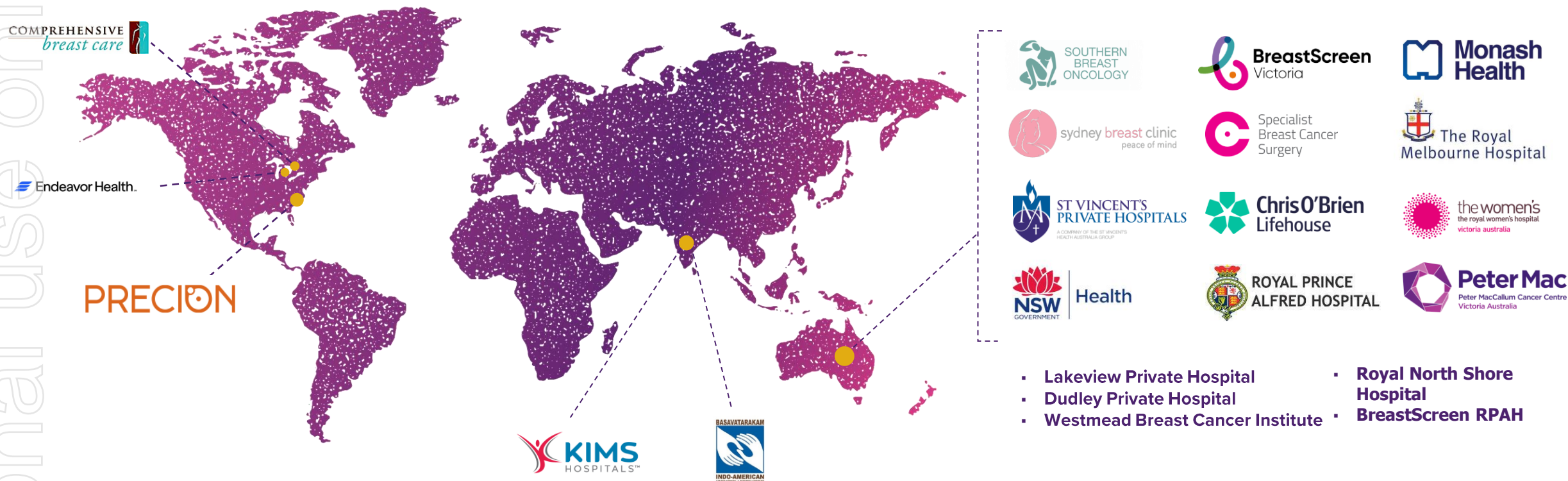
People

- 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 Development
- Appointed MS Cory Dunn 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

BCAL IS WORKING WITH CLINICIANS FROM LEADING CENTRES AROUND THE GLOBE



- Lakeview Private Hospital
- Dudley Private Hospital
- Westmead Breast Cancer Institute
- Royal North Shore Hospital
- BreastScreen RPAH

A pilot study assessing the feasibility of using the BCAL test for early diagnosis of breast cancer in India

CLINICAL ADVISORY BOARD

Eminent and influential Breast Clinicians form a National Key Opinion Leader & Clinical Excellence Forum to enhance trust, provide advice and win the market



Dr David Speakman

Recently stepped down as CMO at Peter MacCallum Cancer Centre. A specialist breast and melanoma surgeon. On the executive of BreastSurg ANZ, and CMO at Breast Screen Victoria.



Prof Bruce Mann

Research Director Breast Cancer Trials Australia. Surgical Oncologist and Specialist Breast Surgeon. He is the Director of Breast Cancer Services at the Victorian comprehensive Cancer Centre.



Dr Corinne Ooi

VMO at Monash BreastScreen and a Foundation Member of BreastSurgANZ, a specialist society for surgeons treating breast cancer. Member of the Australasian Society of Breast Diseases, ANZ Breast Cancer Trials Group and General Surgeons Australia. Head of Breast Service at Monash Health



A/Prof. James French

Specialist General Surgeon who focusses on Breast Surgery and is the Head of Breast Surgery at the Westmead Breast Cancer Institute.

James is also part of the team leading the development of oncoplastic breast surgery



Prof. Elizabeth Elder

Specialist breast surgeon at the Westmead Breast Cancer Institute and privately through Specialist Services at Lakeview Private Hospital. Elisabeth is a surgeon at the forefront of the developing field of oncoplastic breast surgery and former President Australian Society for Breast Disease.



A/Prof. Cindy Mak

Sydney qualified and trained Breast surgeon. Director of Breast Services at Chris O'Brien Lifehouse (Camperdown). She also operates at the Mater Hospital (North Sydney) and Royal Prince Alfred Hospital.



Dr Samriti Sood

Specialist Oncoplastic Breast Surgeon who offers expertise in the management of women with all breast related conditions. Operates at The Mater, Royal North Shore and Northern Beaches.



A/Prof. Gillian Lamoury

Radiation oncologist with a sub specialty in breast cancer. Based at The mater and Royal North Shore.









Dr Sally Baron-Hay

Sally Baron-Hay is a medical oncologist with over 20 years of clinical experience and senior lecturer at the University of Sydney, with clinical appointments at Royal North Shore Hospital in Sydney, North Shore Private Hospital, The Mater Hospital and Genesis Care

Market entry strategy focuses on engaging ~200 breast surgeons across Australia, leveraging our Advisory board network. Subsequently targeting the rest of the Multi-Disciplinary Team (MDT) including partnership with the McGrath Foundation's 204 nurses nation-wide. GPs will be a key focus in a second wave of market engagement

BREASTEST® WILL BE USED AS A SCREENING TOOL

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

MARKET ACCESS: AUSTRALIA SOFT LAUNCH

Launch of BREASTEST®

01



NSW & VIC launch

- Initial focus on Sydney and Melbourne
- Secured agreement with Sydney Breast Clinic
- 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



DRIVING A NEW PARADIGM IN BREAST CANCER
DIAGNOSTICS



Thank you

Jayne Shaw
Executive Chair
jshaw@bcaldiagnostics.com

Shane Ryan
Chief Executive Officer
sryan@bcaldiagnostics.com