



ASX Announcement

3 May 2023

BCAL DIAGNOSTICS OPENS NEW LABORATORY IN SYDNEY AS IT ACCELERATES DEVELOPMENT OF ITS BLOOD SCREENING TOOL

Marks Important Milestone in Commercialisation of Blood Screening Tool that is intended to be used alongside current breast cancer screening tools

[BCAL Diagnostics Limited](#) (ASX:BDX) (BCAL or Company) an Australian-based biotechnology company today announced the opening of its development and clinical service laboratory in Sydney. This step marks an important milestone for the company as it advances commercialisation of its non-invasive blood screening that is initially intended to be used alongside breast cancer screening methods, with results to date demonstrating 91% sensitivity and 80% specificity. The technology will initially complement current imaging technologies, such as the mammogram, while BCAL further progresses the development of a monitoring and screening test suitable for women of all ages and backgrounds in any location.

The laboratory will utilise the newest Liquid Chromatography Mass Spectrometry (LCMS) platforms to continue to advance the findings of the Company's clinical research to-date and the progress made by BCAL Diagnostics' US commercialisation partner, Precion Inc. to establish and validate workflows, test protocols and algorithms for the BCAL blood screening tool. It will also serve as the testing site for the ongoing and planned clinical validation studies and will establish the quality systems and protocols to be compliant with ISO 15189, CLIA accreditation, NPAAC (National Pathology Accreditation Advisory Council) certifications and requirements of the *Therapeutic Goods Act 1989* (Cth).

The successful completion of these studies and receipt of the accreditations will allow the BCAL blood screening tool to be available to the medical community and patients as an in-house developed test, also known as a laboratory-developed test or LDT. Patient samples will be collected and forwarded to BCAL's laboratory, where they will be tested for the proprietary BCAL lipid signature that is expressed by breast cancer cells.

"BCAL is diligently working toward bringing its novel diagnostic tool to women and the opening of our soon to be fully commercial and accredited laboratory brings us one step closer to accomplishing this goal," said Jayne Shaw, Executive Chair of BCAL. *"We plan to use this laboratory for a variety of purposes leading up to and following product approval and availability. We are very excited by the market access opportunities*

that this laboratory provides, not only for current and future tests that may be developed by BCAL, but also for those developed by other companies seeking entry to the Australian market.”

The Company continues to make significant clinical development progress and has conducted multiple studies with more than 1,200 patients. Studies have shown changes to specific lipids in the presence of breast cancer. A poster titled **Lipodomic signature from plasma to detect localised breast cancer** will be presented during the 2023 ASCO Annual Meeting, June 2-6, 2023 in Chicago.

To learn more about BCAL or to participate in BCAL’s research, you can register your interest online at www.bcaldiagnostics.com.

This ASX announcement has been approved for release by the Board of BCAL.

About BCAL Diagnostics Limited (BCAL)

BCAL Diagnostics Limited is an Australian biotechnology company committed to improved health outcomes for women. Over the past decade, BCAL has developed a non-invasive blood screening technology that is initially intended to be used alongside breast cancer screening methods, with results to date demonstrating 91% sensitivity and 80% specificity. The technology will initially complement current imaging technologies, such as the mammogram, while BCAL further progresses the development of a monitoring and screening test 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>

Jayne Shaw
Executive Chair
Jshaw@bcaldiagnostics.com

Guy Robertson
Chief Financial Officer
grobertson@bcaldiagnostics.com

For personal use only