

25 October 2022

BCAL DIAGNOSTICS TO ESTABLISH A DEVELOPMENT AND CLINICAL SERVICE LABORATORY IN SYDNEY

BCAL Diagnostics Limited (ASX:BDX) (BCAL or Company) is pleased to announce it has entered into a commitment to lease for a Sydney facility that will be the Development and Clinical Services Laboratory for the Company.

The founding of this laboratory represents a major step towards the commercialisation of the Company's blood-based test to detect breast cancer. This laboratory will utilise the findings of the Company's clinical studies to date and the outcomes of work being carried out by BCAL's US commercialisation partner Precion Inc. to establish, validate the workflows, test protocols and algorithms for the BCAL breast cancer test.

The laboratory will be the testing site for the ongoing and planned clinical studies and will establish the quality systems and protocols to be compliant with ISO 15189, NPAAC (National Pathology Accreditation Advisory Council) certifications and requirements of the Australian Therapeutics Good Act.

These accreditations will allow the BCAL breast cancer blood test to be available to the medical community and patients as an in-house developed test, also known as an LDT. Patient samples will be collected and forwarded to this laboratory where they will be tested for the proprietary BCAL lipid signature that is indicative for breast cancer.

BCAL has taken the decision to establish this laboratory as the fastest and most efficient way to establish market access for the BCAL test. As a fully commercial and accredited laboratory, it also provides the opportunity for achieving rapid market access not only for current and future tests that may be developed by BCAL, but also for those developed by other companies seeking an entry to the Australian market.

Jayne Shaw, Executive Chair of BCAL commented: *"The establishment of a development and clinical laboratory is a key step in making the BCAL blood test for breast cancer available to Australian women, providing an additional important tool for clinicians to screen and diagnose breast cancer. Over the next several months we will be hiring personnel and certifying the necessary equipment with the aim to have the laboratory fully functional by the end of February 2023."*

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

ENDS

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About BCAL Diagnostics Limited (BCAL)

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, with results to date demonstrating 91% specificity and 87% accuracy. 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 global integrated cancer care and cardiac provider GenesisCare to conduct clinical research 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/>