



ASX Announcement

11 September 2023

BCAL LOCKS DOWN CRUCIAL BREAST CANCER SIGNATURE

BCAL Diagnostics Limited (ASX:BDX) (BCAL or Company), an Australian-based biotechnology company developing a blood test for breast cancer, is pleased to announce that it has met a major milestone in its development pathway to launching a blood test for breast cancer.

BCAL's test is based on changes in the lipid (fat) composition that occur in the blood of women who develop breast cancer. The sum of the changes that occur in the blood of patients with breast cancer, defines a breast cancer signature that can be detected by the BCAL BREASTEST™. BCAL has now identified and confirmed the key 20 lipids that make up this signature. These 20 lipids provide the basis for the proprietary BREASTEST™ that will be launched in 2024. To identify the signature, BCAL has compared lipid profiles in samples of blood from more than 2000 biopsy-confirmed breast cancer patients and healthy control subjects.

The spectrum of lipids found in human blood plasma is a complex inventory of more than 1000 distinct types. The different lipids in blood and tissue play essential roles in cell structure, energy utilisation and even in messaging between cells. The transformation of cells from normal to cancer is driven in part, and accompanied by, changes in the production and metabolism of some classes of lipids and it is these changes that constitute the BREASTEST™ lipid signature.

Using laboratory instrumentation to separate the lipids in the blood and algorithms developed by the application of Machine Learning (a type of artificial intelligence), BCAL can detect and measure, in each blood sample, the profile of the 20 lipids making up the test signature and identify whether or not the profile reflects the presence of breast cancer. The identity and application of the 20-lipid signature for the detection of breast cancer is the subject of a patent application.

BCAL Executive Chair, Jayne Shaw, commented "*The confirmation of the identity and locking down of the lipids involved with the breast cancer signature is a crucial step towards providing the BCAL BREASTEST™ to the clinical community involved with the screening, care and management of breast cancer patients. Next steps involve the clinical validation of the test performance*".

BCAL CEO, Dr John Hurrell commented: "*This step is the culmination of more than 10 years dedicated efforts by BCAL Founders, Jayne Shaw and Hon. Ron Phillips AO, the research team at BCAL and the support from our many clinical and scientific advisors. With the identification of the lipids constituting the breast cancer signature, the completion of setting up and equipping our development and clinical services laboratory where commercial testing will be carried out, and supported by the additional capital raised recently, we are now poised to complete the development of the BREASTEST™ and have it available to the clinical community next year.*"

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

ENDS

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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, with results to date demonstrating 90% specificity and 85% 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.

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