ASX Announcement

17 November 2026

BCAL expands breast cancer biomarker program and advances scientific validation

Highlights

- Human Research Ethics Committee approval received to expand BCAL's existing breast cancer sample collection and analysis program to include multiomic assay development.
- Manuscript outlining BCAL's translational lipidomics framework published in the peer-reviewed journal *Scientific Reports* (Nature Portfolio).
- Further scientific paper submitted to *Communications Medicine* (Nature Portfolio) and currently under revision following peer review.
- Abstract accepted San Antonio Breast Cancer Symposium to be held in December 2026.

BCAL Diagnostics Limited (ASX: BDX), an Australian healthcare company pioneering diagnostics for early detection of cancer, has received expanded ethics approval enabling the collection and analysis of samples for multiomic assay development in breast cancer screening, alongside further scientific validation of its lipidomics platform through the publication of research in the peer-reviewed journal *Scientific Reports*.

These developments strengthen BCAL's clinical development pathway, expand the Company's ability to investigate additional biomarkers for future diagnostic applications, and provide further external validation of the science underpinning BREASTESTplus™ and BCAL's broader diagnostic platform.

Ethics approval expands multiomic research capability

BCAL has also received ethics approval for an amendment to its existing breast cancer research program, enabling the collection and analysis of samples for multiomic assay development for breast cancer screening. The approval enables BCAL to expand its biomarker research beyond lipidomics to include epigenomic biomarkers being investigated, supporting the development of future generations of breast cancer diagnostic assays.

Peer-reviewed scientific publication

BCAL has received notification that its manuscript, "A Translational LC-MS/MS Framework for Lipid Biomarker Identification and Quantification in Human Plasma", has been published in the industry leading *Scientific Reports*, a peer-reviewed Nature Portfolio journal and e– print in BioRxiv. https://www.nature.com/articles/s41598-026-67559-x

The paper describes the rigorous scientific process BCAL used to take its breast cancer lipid biomarkers from initial discovery through to a precise, quantitative laboratory assay, providing a clear and repeatable framework for moving from research findings towards a test suitable for clinical use. This is an important milestone for BCAL and its referring network, as it demonstrates that the lipid signals underpinning the BCAL test can be measured reliably and reproducibly. Publication provides further external peer-reviewed validation of the scientific and analytical framework supporting BCAL's lipidomics-based diagnostic development program.

A second paper, *"A Cross-Cohort Validated Plasma Lipid Biomarker Assay for Early Breast Cancer Detection Using Machine Learning"*, has been submitted to *Communications Medicine* (Nature Portfolio) and is currently under revision following peer review. Building on the analytical framework published in *Scientific Reports*, this paper applies the lipid assay to patient samples from international cohorts and uses machine learning to detect early-stage breast cancer from a blood

sample. Together, the two papers take BCAL's platform from a robust laboratory method through to its clinical application. A preprint is available at:

https://www.medrxiv.org/content/10.64898/2026.04.23.26351564v1

Clinical translation of BREASTESTplus v2

Dr Mark David, BCAL's Director of Mass Spectrometry and Clinical Scientist, recently presented a poster titled "Clinical Translation of Targeted Lipidomics: Validation of BREASTESTplus 2 for Early Breast Cancer Detection" to the Australian Lipid Meeting 7 and 5th International Lipidomics Society Conference, held in Perth from 18–21 October 2026.

A further abstract, "A Novel Blood-Based Lipidomic Assay for Loco-Regional Breast Cancer Recurrence", has been submitted to the key annual San Antonio Breast Cancer Symposium to be held in December 2026 and accepted.

BCAL CEO Anne-Louise Arnett said: *"Our expanded ethics approval provides us with the ability to investigate complementary multiomic biomarkers in breast cancer. This has the potential to strengthen future generations of BREASTESTplus™ and broaden the diagnostic applications we can pursue from our scientific platform."*

In addition, the acceptance of our work in key scientific and clinical peer reviewed publications and key clinical Conferences and Symposia is an important external validation of the scientific and analytical framework underpinning BCAL's lipidomics platform and its translation into clinically relevant diagnostic tests."

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

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About BCAL Diagnostics

BCAL is an Australian health care company engaged in early cancer detection. BCAL launched its first test BREASTEST*plus*™ as a 'rule-out' test designed to be used in the clinical evaluation of breast disease for women with dense breasts. BREASTEST*plus*™ is a simple, non-invasive blood test used in conjunction with mammography to improve screening and diagnostic outcomes for breast health in women.

BCAL holds an exclusive license with ClearNote Health Inc., a US-based precision diagnostics company, for the sale and distribution of Avantect Pancreatic, Avantect Ovarian and Avantect multi-cancer blood tests in Australia and New Zealand.

BCAL is headquartered in Sydney, Australia and listed on the Australian Securities Exchange (ASX: BDX). For more information: https://www.bcaldiagnostics.com/ or contact info@bcaldiagnostics.com.