

ASX Announcement

5 November 2024

BCAL Diagnostics to commence phase one of the commercial launch and anticipates positive news from NATA assessment

- **First BREASTEST® to be made available to patients commercially**
- **Sydney Breast Clinic to be initial launch site**
- **Follows successful publication in an international peer-reviewed journal**

BCAL Diagnostics Limited (ASX: BDX) (“BCAL” or “the Company”) confirms that it will soon commence phase one of the commercial launch of its first BREASTEST® product, in partnership with the Sydney Breast Clinic, in Q1 CY25.

A phased commercial roll-out, with phase one restricted to the Sydney Breast Clinic, will provide benefits to BCAL prior to expanding market entry across multiple sites in Australia in phase two. Learnings from the experience gained from both clinicians and patients in phase one will ensure vital improvements are made to the commercial program, before accelerating into phase two.

As planned, BREASTEST® will be available to patients as an adjunct to the standard mammogram, with the intention of providing improved results and greater surety to clinicians and patients.

The NATA assessment of the Company’s North Ryde laboratory went well, however a request for additional information now provided, has added several weeks to the approval process.

The company has recently announced the publication of an original research article in the International Journal of Molecular Sciences (<https://www.mdpi.com/1422-0067/25/21/11559>), which highlights the results from early discovery work that forms the basis of the BREASTEST® technology.

BCAL CEO, Shane Ryan, said: “These are significant milestones for BCAL and the first time our novel breast cancer screening test will be available to women. Following a successful phase one launch, we will be looking to accelerate BREASTEST® market entry, and we are already in discussions with additional private, multi-disciplinary breast screening sites across Australia.”

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

ENDS**For further information:****Jayne Shaw**Executive Chair
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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 blood test for the detection of breast cancer, with results to date demonstrating excellent performance independent of breast tissue density. 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/>

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