

ASX Announcement

19 November 2025

Early cancer detection tests - clinical, regulatory and commercial update

Highlights

- **BCAL on track to sell Pancreatic and Ovarian cancer tests in January 2026**
- **BCAL partner ClearNote secures UK regulatory approval for Avantect® Pancreatic and Ovarian test**
- **BREASTESTplus™ expands addressable market to women with breast density C based on new clinical data**
- **Telehealth pathway for early-detection patients to open in Q1 2026. Individuals can register for updates at earlydetection.com.au**

BCAL Diagnostics Limited (ASX: BDX) (“BCAL” or the “Company”), a healthcare company engaged in early cancer detection, provides an update on expanded clinical, regulatory and commercial pathways for its early detection cancer tests.

BCAL Chief Executive Officer Shane Ryan said: *“Our partnership with ClearNote Health is transformative as it expands our portfolio into the early detection of multiple cancers. The Australian medical community will benefit from a suite of early diagnostic tests that will materially improve outcomes for patients.*

“ClearNote’s recent global achievements, including UK regulatory approval, selection for the US Vanguard Trial, advances in US reimbursement, and the priority Fast-Track submission for pancreatic cancer, significantly strengthen the commercial outlook for the Avantect® portfolio. These milestones provide momentum for the Australian launch of Avantect® in January 2026.

“We continue to make strides in expanding the reach of BREASTESTplus™ with new data confirming significant expansion in addressable market. With BREASTESTplus™ building clinical traction, and the Avantect® tests preparing for domestic launch, BCAL is well positioned to become an Australian leader in early cancer detection.”

Avantect® pancreatic and ovarian tests on track for launch January 2026

ClearNote has made significant regulatory, clinical and commercial progress internationally, strengthening the global validation of its epigenomic platform ahead of its Australian launch in January 2026.

Through its exclusive licence with ClearNote Health Inc., BCAL will introduce the Avantect® Pancreatic and Avantect® Ovarian blood tests in Australia (see [ASX announcement](#) 18/09/2025).

Ahead of the Australian launch, updated clinical performance data¹ demonstrates major improvements in early-stage detection across both the Avantect® Pancreatic and Avantect® Ovarian

¹ Evaluation of a cell-free DNA (cfDNA) blood test for early detection of pancreatic cancer in high-risk individuals. Poster presentation European Society For Medical Oncology (Abstract 2245P). ClearNote Health, October 2025.

tests. The Avantect® Ovarian Test will initially be offered to women with familial or genetic risk, including BRCA mutation carriers and those with strong family histories of breast or ovarian cancer.

The pancreatic test has demonstrated high sensitivity and improved specificity at Stages I–II, where no reliable blood-based diagnostic currently exists, with strong performance in patients presenting with non-specific abdominal, gastrointestinal or metabolic symptoms. In a validation cohort of 1,445 tests, sensitivity of the test was 82.6% at a specificity of 97.5%.

One key application of the Avantect® Pancreatic test is for surveillance of patients who have been recently diagnosed with type 2 diabetes. During the first three years following diagnosis, pancreatic cancer is 6-8 times more common than in a healthy population. In Australia, there are over 20,000 new type 2 diabetes diagnoses annually, producing a 60,000-person population in addition to the population with a known familial or genetic risk of pancreatic cancer

As presented at ESMO 2025 in Berlin last month, the Avantect® Pancreatic test is being evaluated in a 15,000 participant study in the UK (the SAFE-D trial) for new-onset type 2 diabetes patients, the results of which are anticipated to demonstrate the clinical merits of semi-annual testing for newly diagnosed diabetics.

In a separate study reported at ESMO², the Avantect® test was used under evaluation for its potential to detect Pancreatic ductal adenocarcinoma in high-risk individuals enrolled in the Pancreatic Cancer Early Detection (PRECEDE) Consortium. Over 612 samples, interim results showed a real-world use performance that exceeded the validated performance and demonstrated the potential of Avantect® Pancreatic for surveillance in high-risk populations.

In Australia, over 120,000 people are estimated to have a genetic condition that increases the risk of developing pancreatic cancer. BCAL is working with Pancare Foundation, who support patients and families dealing with upper GI cancers including pancreatic cancer, to inform the community about the benefits of early detection.

Together, these two clinical applications create an addressable market exceeding \$250 million pa in Australia for the pancreatic test alone.

Complementing these findings, a health economic analysis (conducted with the Mayo Clinic and the Arizona Centers for Digestive Health reported at the International Society for Pharmacoeconomics and Outcomes Research conference in Barcelona in November 2024) concluded that using Avantect® to monitor newly diagnosed type 2 diabetes patients aged 50 and over is cost-effective and has the potential to improve survival outcomes.

BCAL is collaborating with Professor Jaswinder Samra, eminent pancreatic surgeon at Royal North Shore Hospital and Macquarie University Hospital and a leading Australian authority on pancreatic and hepatobiliary disease, to support development of local clinical pathways. Professor Samra has authored more than 400 peer-reviewed publications and led numerous clinical trials in pancreatic cancer, biliary tract disease, and complex abdominal surgery.

² *University Hospital Southampton NHS Foundation Trust & ClearNote Health (2025). SAFE-D Trial design: Targeted pancreatic cancer surveillance to evaluate resectability rate and stage shift in patients with new onset diabetes. Scientific poster (Abstract 2255TiP)*

Commenting on emerging data, Professor Samra noted: *“Epigenomic blood testing represents one of the most promising advances for pancreatic cancer in decades. Detecting cancer when it’s still operable can transform survival outcomes for patients who currently face diagnosis too late for curative treatment.”*

ClearNote achieves global milestones

ClearNote’s epigenomic platform has been selected to participate in the US Vanguard Trial, one of the largest federally supported multi-cancer early-detection studies, providing independent large-scale validation ahead of Australian deployment. In parallel, ClearNote achieved significant progress toward payer reimbursement in the United States, including acceptance of clinical data packages and agreements on reimbursements by major US insurance companies, and the submission of a priority fast-track application for Avantect® Pancreatic under the relevant US expedited review pathway.

ClearNote has secured regulatory approval in the United Kingdom for the Avantect® testing platform, enabling clinical deployment across the UK.

BCAL releases commercial update of BREASTESTplus™

BCAL Diagnostics has enhanced the clinical application of BREASTESTplus™, with recent data analysis enabling the expansion of its clinical coverage of a broader group of women being evaluated for breast cancer. BREASTESTplus™ is used as a ‘rule-out test’ for breast cancer in conjunction with the standard of care mammogram. BREASTESTplus™ launched earlier in 2025 with clinical application for ruling out patients, with breast density class D, who do not have breast cancer.

Following the successful conclusion of a recent clinical study of 613 Australian women with high breast density, BREASTESTplus™ now delivers 90% sensitivity with a projected Negative Predictive Value (NPV) of 99.7%, and can now be used by doctors on patients with either Breast D and C breast density.

This expands clinical use to cover approximately 50% of the women screened for breast disease. Initially available across Sydney and one site in Melbourne, plans are now underway to expand availability in Melbourne and Brisbane, giving more doctors and patients access to BREASTESTplus™.

Access and engagement

BCAL will launch a dedicated telehealth service in Q1 2026 to connect interested individuals with qualified clinicians for early-detection consultations. To register for further information visit the www.bcaldiagnostics.com or register at earlydetection.com.au

BCAL AGM

Further information on BCAL and ClearNote’s partnership will be presented at the Annual General Meeting on 28 November 2025 at 11am.

Register [here](#).

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

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About BCAL

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 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 and Avantect Ovarian cancer blood tests in Australia and New Zealand.

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