

ASX Announcement

18 September 2025

BCAL and ClearNote partner to bring cutting-edge early cancer detection blood tests to Australia

Highlights

- **ClearNote Health has selected BCAL to deliver their cutting-edge Avantect® Pancreatic Cancer Test and Avantect Ovarian Cancer Tests entering into an exclusive licence agreement for the Australian and NZ market**
 - **ClearNote Health is a US precision diagnostics company, offering CLIA/CAP-accredited testing in the United States and UKCA-marked tests in the United Kingdom**
 - **ClearNote Health currently distributes its tests across 70 countries through licensee partners**
- **Tests to be integrated into BCAL's existing Australian medical distribution networks**
- **Agreement positions BCAL to become a leader in blood-based cancer screening, saving lives through early detection in late-discovered and difficult to treat cancers.**

BCAL Diagnostics Limited (ASX: BDX) ("BCAL") has entered into an exclusive licence agreement with ClearNote Health Inc. ("ClearNote Health"), a US-based precision diagnostics company, for the distribution of ClearNote Health's pancreatic and ovarian cancer blood tests in Australia and New Zealand.

The agreement provides BCAL with rights to distribute and commercialise the tests in Australia and New Zealand and covers all future tests based on ClearNote Health's proprietary epigenomics testing platform. BCAL will leverage its existing partnership networks for distribution. BCAL's growing portfolio of oncology offerings creates new opportunities to work with more doctors and build new strategic partnerships.

BCAL will integrate these new blood tests into its existing and expanding distribution network, which includes a global leader in pathology and diagnostic services, Cancer Care and Associates, and Sydney Breast Clinic. Commencing in Q1 CY26, the agreement is for an initial period of two years, with an option to extend for a further six years.

Strategically, the agreement expands BCAL's position as a leader in cancer detection, complementing its breast cancer test program by adding high-value, clinically validated cancer tests to BCAL's pipeline.

BCAL Executive Chair Jayne Shaw said: *"We are excited to partner with ClearNote Health to bring advanced diagnostic technology for early detection of cancer to Australia. ClearNote Health is a leader in epigenomic-based multi-cancer detection. Their expertise, data scale, and international validation will accelerate BCAL's growth. Our agreement with ClearNote is transformational. It positions us as a leader in early pancreatic and ovarian cancer detection and significantly broadens our reach beyond early breast cancer detection. Pancreatic cancer is an excellent example of the power of early detection. Only 4% of patients survive a late-stage diagnosis, while 80% survive if the cancer is detected at Stage 1A, where ClearNote Health's Avantect test is designed to work".*

"Ovarian and pancreatic cancer claim around 5,000¹ Australian lives each year. There is an urgent need for non-invasive and accurate blood-based diagnostic solutions to detect cancers with high mortality and low early-detection rates".

"Strategically, patients at risk of pancreatic and ovarian cancers overlap significantly with the breast cancer screening patients BCAL already serves, and the clinicians supporting these patients understand the importance of early-stage detection across multiple cancer types. This creates a complementary and synergistic value in offering these tests. Together with our capable diagnostic partners, we are well positioned to make these life-saving tests accessible to patients and clinicians across Australia and New Zealand."

ClearNote Health CEO Dave Mullarkey said: "We are pleased to bring ClearNote Health's technology to Australia and New Zealand in partnership with BCAL. ClearNote Health and BCAL share a common vision to transform how cancers are detected and diagnosed. BCAL's deep expertise, strong local network, and alignment with our technology-driven approach make them the ideal partner to deliver earlier, more accurate detection for patients and reduce the burden of high-mortality cancers on Australia's healthcare system."

Founded in 2016 in California, ClearNote's core technology was developed by scientists in the Stephen Quake laboratory at Stanford University. The company's platform builds on the latest advances in artificial intelligence and bioinformatics to measure active biological differences between cancer and healthy cells in a blood sample. Its highly sensitive, non-invasive Avantect [pancreatic](#) and [ovarian](#) diagnostic tests may identify cancers in high-risk patient populations earlier than conventional approaches, when patients could be more likely to benefit from treatment. ClearNote Health offers CLIA/CAP-accredited testing in the United States and UKCA-marked tests in the United Kingdom, and currently distributes through 70 countries via local licensee partners. To date, more than 20,000 patient samples have been used to optimise ClearNote Health's early detection tests to detect a cancer signal.

In addition to published peer-reviewed studies, ClearNote Health continues to generate real-world evidence from patients in the US and Europe, demonstrating the following performance:

- **Avantect Pancreatic Cancer Test:** Demonstrated sensitivity of ~68% and specificity of ~97% in peer-reviewed clinical studies, enabling detection at earlier, more treatable stages.
- **Avantect Ovarian Cancer Test:** Validated sensitivity exceeding 78% and specificity above 94%, providing a non-invasive alternative to traditional early detection methods.

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

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¹ Cancer Australia. 1,050 deaths from ovarian cancer 2023; 3,902 deaths from pancreatic cancer in 2024.

About ClearNote Health

ClearNote Health is a privately held company dedicated to improving early detection and monitoring for some of the deadliest forms of cancer. Developed by scientists in the Stephen Quake laboratory at Stanford University, the company's patented core [Virtuoso™ epigenomics platform](#) builds on the latest advances in artificial intelligence and bioinformatics to measure active biological differences between cancer and healthy cells in a blood sample. Its highly sensitive, non-invasive Avantect® [pancreatic](#) and [ovarian](#) diagnostic tests may identify cancers in high-risk patient populations earlier than conventional approaches, when patients may be more likely to benefit from treatment. ClearNote Health's headquarters and CLIA-certified, CAP-accredited laboratory are located in San Diego. For more information, visit www.clearnotehealth.com or follow the company on [LinkedIn](#).

About BCAL

BCAL is an Australian biotechnology company engaged in early multi-cancer detection. BCAL maintains an exclusive licence agreement with ClearNote Health Inc. ("ClearNote Health"), a US-based precision diagnostics company, for the distribution of ClearNote Health's pancreatic and ovarian cancer blood tests in Australia.

BCAL is also focussed on advancing early and accurate breast cancer detection via BREASTEST plus™ a non-invasive, lipid-based 'rule-out' test designed to be used in women with dense breasts and alongside mammography to improve screening and diagnostic outcomes for women.

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