



BCAL Hits High Note with ClearNote Deal

BCAL Diagnostics Ltd

BCAL has signed an exclusive licence with ClearNote Health to distribute ClearNote's Avantect Pancreatic Cancer Test and Avantect Ovarian Cancer Test in Australia and New Zealand. Launch is targeted for the first quarter of 2026, and the deal is for an initial 2-year term with an option to extend 6 years. The deal also covers future tests from ClearNote's epigenomics platform. BCAL will integrate these tests into its existing Australian distribution networks.

Strategic Fit

This agreement marks a pivotal strategic evolution for BCAL, transforming it from a single-asset company focused on breast cancer into a diversified diagnostics platform. By adding two high-value tests for cancers with significant unmet clinical needs, BCAL materially de-risks its commercial pathway. This expansion creates multiple, independent revenue streams and repositions the company as an emerging leader in non-invasive diagnostics for cancers that critically impact women's health.

BCAL will leverage the entire go-to-market infrastructure already established for its BREASTEST plus™ product. The new pancreatic and ovarian cancer tests can be rolled out as a "plug-and-play" offering through existing partnerships with Sonic Healthcare/DHM for sample collection and Cancer Care Associates (CCA) for specialist distribution. This operational synergy allows BCAL to add new revenue lines with minimal incremental spending, dramatically accelerating its potential path to profitability.

Addressing a Critical Unmet Need with Validated Tests

The agreement targets two cancers with a significant unmet clinical need; pancreatic and ovarian cancers cause approximately 5,000 deaths in Australia each year, primarily due to late-stage diagnosis. For pancreatic cancer, the 5-year survival rate plummets from 44% for localised disease to just 3% once it has spread. Similarly, for ovarian cancer, survival drops from 92% to 32% with late-stage detection. The licensed Avantect® tests are designed to address this challenge:

- Avantect® Pancreatic Cancer Test: Has demonstrated sensitivity of ~68% and specificity of ~97% in peer-reviewed clinical studies.
- Avantect® Ovarian Cancer Test: Has validated sensitivity exceeding 78% and specificity above 94%.

Crucially, BCAL is licensing a platform with significant US commercial and regulatory validation. ClearNote's pancreatic test has received Breakthrough Device Designation from the US FDA, and its platform was selected for the US National Cancer Institute's (NCI) 24,000-person Vanguard study. Both tests have secured reimbursement pricing from the US Centers for Medicare & Medicaid Services (CMS) at US\$1,160 per test, providing a strong commercial precedent.

Valuation

Without key commercial terms of the deal published, we wait to update our fair valuation of BCAL. Fair valuation remains unchanged at \$0.25, though we will provide an update to this in due course.

Recommendation	Spec Buy
Share Price	\$0.068
Fair Valuation	\$0.25
TSR	268%

Company Profile

Market Cap	\$24.9m
Enterprise Value	\$22.5m
SOI (undiluted)	365.97m
Free Float	61.3%
ADV (3-month)	~\$15k
52-Week Range	\$0.052 - \$0.14

Price Performance



Company Overview

BCAL 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 excellent performance. The test is initially designed to complement current imaging technologies, such as the mammogram. With more than two million new cases of breast cancer diagnosed globally each year, a substantial opportunity exists for BCAL to improve patient outcomes.

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Beyond Breast Cancer

Until this agreement, BCAL's corporate strategy and valuation were intrinsically tied to the success of a single asset: its proprietary lipid-based blood test for breast cancer, BREASTEST plus™. While promising, a single-product focus carries inherent risks, including binary outcomes related to clinical adoption, reimbursement challenges, and the emergence of competitive threats within a specific indication. The diversification into pancreatic and ovarian cancer diagnostics is a sophisticated strategic manoeuvre that mitigates these risks by creating multiple, independent pathways to commercial success. By adding two new, distinct products, BCAL spreads its commercial risk profile and creates several shots on goal for revenue generation, building a more resilient and less volatile investment case. A potential delay in one program, such as the broader GP uptake of BREASTEST plus™, could be offset by strong early adoption of the Avantect® Pancreatic Cancer Test among oncology specialists, thereby insulating the company's overall progress.

The Added Benefit to Clinicians

This deal allows BCAL to evolve from a product vendor into a comprehensive platform provider for clinicians. The announcement correctly highlights that the at-risk patient cohorts for pancreatic and ovarian cancers significantly overlap with BCAL's existing breast screening population, creating "complementary and synergistic value". This synergy extends beyond simple cross-selling; it fundamentally changes the nature of the conversation with healthcare providers. BCAL can now approach a specialist – such as an oncologist, a gastroenterologist, or a GP with a focus on women's health – with a cohesive suite of advanced, non-invasive diagnostic tools.

ClearNote's Validated Technology

BCAL is licensing a sophisticated platform that has already achieved gain external validation in the US. ClearNote Health was founded on science from the Stephen Quake laboratory at Stanford University, a world-renowned institution for genomics and molecular biology. Its core Virtuoso™ epigenomics platform, which measures 5-hydroxymethylcytosine (5hmC) patterns in circulating cell-free DNA, represents a novel and powerful approach to liquid biopsy.

ClearNote's platform was selected by the US National Cancer Institute (NCI) for its 24,000-person, four-year Vanguard multi-cancer early detection (MCED) study, part of the US Cancer Moonshot initiative. This selection implies the technology successfully passed a rigorous head-to-head technical assessment against competing platforms and is considered highly promising by leading federal cancer research authorities. Furthermore, the Avantect® Pancreatic Cancer Test has received Breakthrough Device Designation from the US Food and Drug Administration (FDA), a status reserved for technologies that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases. For clinicians and investors in Australia, these credentials serve as crucial third-party validation, substantially reducing the perceived technology risk and shortening the due diligence cycle for potential adopters.

Commercial De-Risking

A primary hurdle for any new diagnostic test is establishing its economic value to payers. ClearNote has successfully navigated this challenge, having secured active CPT (Current Procedural Terminology) codes and, most importantly, final pricing from the Centers for Medicare & Medicaid Services (CMS) of US\$1,160 per test for both the pancreatic and ovarian assays. CMS is the largest healthcare payer in the US. When BCAL launches these tests in the Aus & NZ private-pay market, it can anchor its pricing strategy to a benchmark validated by a major US government payer. This precedent dramatically strengthens its negotiating position with local private health insurers and provides a powerful justification for its pricing structure, significantly de-risking the future revenue potential of the licensed products.



Feature	Avantect Pancreatic	Avantect Ovarian
Indication	Early detection in high-risk populations	Early detection in high-risk populations
Technology	Virtuoso™ Epigenomics (5hmC in cfDNA)	Virtuoso™ Epigenomics (5hmC in cfDNA)
Sensitivity	68%	78%
Specificity	97%	94%
US FDA Status	Breakthrough Device Designation	N/A
US Payer Status	CPT Codes & CMS Pricing: US\$1,160	CPT Codes & CMS Pricing: US\$1,160

Addressing a Critical Unmet Need

Pancreatic and ovarian cancers are notoriously difficult to detect in their early stages, leading to diagnoses that often occur after the disease has metastasized, at which point treatment options are limited and prognoses are grim. In Australia alone, these two cancers are responsible for approximately 5,000 deaths each year.

Challenges in Pancreatic

For pancreatic cancer, the disparity in outcomes is staggering. According to data from the US National Cancer Institute's SEER program, the five-year relative survival rate for patients diagnosed with localized pancreatic cancer is 44%. However, if the cancer is not detected until it has spread to distant parts of the body, that survival rate plummets to just 3%. This more than 14-fold difference in survival underscores the desperate need for diagnostic tools that can identify the disease while it is still confined to the pancreas and potentially amenable to curative surgery. As noted in the announcement, the survival benefit is dramatic: while only 4% of late-stage patients survive, that figure can rise to 80% if the cancer is detected at Stage 1A, the exact window where the Avantect® test is designed to work.

Challenges in Ovarian

A similar, though less extreme, dynamic exists for ovarian cancer. It is the deadliest of all gynaecological cancers, primarily because only about 20% of cases are found at an early stage. For invasive epithelial ovarian cancer, the most common form, the five-year survival rate for localized disease is an encouraging 92%. Yet, for distant-stage disease, this figure falls to 32%. This nearly three-fold improvement in survival with early detection highlights a critical gap in the current standard of care, where vague symptoms often lead to significant diagnostic delays.

Further compounding the challenge in ovarian cancer is the limitation of current frontline imaging techniques. While a transvaginal ultrasound (TVUS) can effectively identify a mass or abnormality on an ovary, it is an unreliable tool for determining whether the growth is malignant or benign. This diagnostic ambiguity creates a significant clinical dilemma, as the only way to definitively diagnose ovarian cancer is through invasive surgery to obtain a tissue biopsy. Consequently, many women with benign cysts may undergo unnecessary surgical procedures, while the need for surgery to confirm a diagnosis can delay treatment for those who do have cancer. This gap highlights the urgent need for non-invasive tests that can more accurately stratify risk and help clinicians distinguish between benign conditions and early-stage cancer without resorting to surgery.

Cancer Type	5yr Survival: Diagnosed at Localised Stage	5yr Survival: Diagnosed at Latter Stage	Early Detection 'Uplift'
Pancreatic	44%	3%	>14x
Ovarian	92% (invasive epithelial)	32% (invasive epithelial)	~3x



Leveraging Existing Go-to-Market Infrastructure

The largest barriers to entry for a new diagnostic are often commercial, not technical: building a sales force, establishing collection and logistics networks, and gaining access to prescribing clinicians. BCAL has already done a lot of the heavy lifting in building this infrastructure for the launch of BREASTEST plus™.

Our previous update report detailed BCAL's national collection agreement with Sonic Healthcare, which provides immediate access to 93 Douglass Hanly Moir (DHM) pathology collection centres across Sydney. This partnership solves the critical "last mile" problem of sample collection, making the tests accessible to a broad patient population. Concurrently, BCAL has established a national distribution partnership with Cancer Care Associates (CCA), one of Australia's leading networks of integrated oncology clinics, creating a direct channel to cancer specialists and high-risk patients. The ClearNote announcement explicitly confirms that the new pancreatic and ovarian cancer tests will be integrated directly into these existing networks, with a targeted launch in Q1 CY26.

This creates a "plug-and-play" operational model. The workflow for the Avantect® tests is identical to that of BREASTEST plus™: a clinician orders the test, the patient provides a blood sample at a partner collection site (like a DHM clinic), and the sample is transported to a central laboratory for analysis. BCAL can simply add the Avantect® tests to the menu of services offered through its established partners. A phlebotomist at a Sonic centre can draw an extra tube of blood during a single patient visit. An oncologist at a CCA clinic can order from the same portal they use for BREASTEST plus™. A BCAL sales representative can discuss the utility of three complementary tests during a single visit to a specialist's office.

This operational leverage is a powerful value driver. BCAL has already incurred the significant fixed costs and corporate effort required to establish these critical logistics and sales channels. The ClearNote tests can now be rolled out through these same "pipes" with minimal incremental capital expenditure. This allows BCAL to capture revenue from the new tests at a potentially higher margin (net of licensing fees) than if it had to build a new commercial infrastructure from scratch. This highly scalable, capital-efficient model dramatically accelerates the company's path to profitability by adding new, high-value revenue streams on top of a largely fixed cost base.

Effect on Valuation

Given the lack of explicit detail on commercial terms, an update to fair valuation is beyond the scope of this report. Regardless, the licensing agreement with ClearNote Health materially expands BCAL's revenue potential.

The serviceable addressable market is substantial. In Australia, there are an estimated 4,641 new cases of pancreatic cancer and 1,786 new cases of ovarian cancer diagnosed annually. However, these incidence figures represent only a fraction of the total market. The primary market for these tests will be high-risk individuals undergoing surveillance, a much larger cohort that includes patients with a family history, specific genetic mutations (e.g., BRCA1/2), or other predisposing conditions. By offering a suite of tests, BCAL can also increase the average revenue per clinical engagement and per patient. The ability to offer a triad of tests – breast, ovarian, and pancreatic – positions BCAL to capture a greater share of the diagnostic spend for at-risk individuals, accelerating its overall revenue ramp far beyond what was achievable with a single product.



Key Risks

Centralised Testing Model

BREASTEST plus™ is run centrally in BCAL's Sydney lab; all samples must be transported and kept stable. Any logistics failure – temperature excursions, courier delays, batching issues – will elongate turnaround times and erode clinician confidence, directly impacting re-orders and uptake.

Reimbursement & Margin Pressure

The fee-for-service collection model widens access but compresses per-test gross margin. In the absence of MBS/Medicare coverage, private-pay pricing may need to trade margin for volume until scale reduces unit costs; mix and payer dynamics (especially in the US) keep near-term earnings sensitive.

Adoption & Execution Risks

Changing clinical behaviour takes time. Slower GP conversion, clinic onboarding or patient acceptance would push out the adoption curve; at the same time BCAL must scale customer support, lab capacity and quality systems without compromising service levels.

Operational Dependency

Reliance on Sonic and other partners introduces third-party execution risk. Variability in staff training, sample handling or changes to commercial terms could disrupt volumes and economics; tight SLAs, auditing and diversified collection options are key mitigants.

Intellectual Property

Challenges to BCAL's intellectual property or third-party claims over biomarkers, methods or software could increase legal costs, limit market scope or necessitate design-around.

Key-Person Risk

Execution requires specialist commercial, lab and regulatory talent; loss of key leaders or slower hiring could delay milestones and scaling.

Competition Risk

Advances in alternative blood-based or imaging-adjacent diagnostics (proteomics, ctDNA, AI-enhanced imaging) could pressure share or pricing, particularly if rivals secure guideline or payer support sooner.

Data Privacy

Centralised analysis depends on secure, always-on lab information systems; a material outage, breach or data-integrity incident could disrupt operations and erode clinician confidence.

Regulatory Risks

Any shift toward tighter FDA control of LDTs, or new state-level requirements, could increase time and cost to scale CLIA testing, alter launch sequencing, or necessitate additional studies.

Real World Performance

If real-world sensitivity/specificity under routine clinical conditions lag published results, uptake could slow and medico-legal risk (from false negatives/positives) could rise, affecting brand and adoption.



Financial Statements & Forecast

Income Statement						Statement of Cashflows					
A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e	A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e
Revenue	-	0.03	0.27	0.67	1.29	Net profit for period	-6.40	-7.23	-8.23	-9.76	-9.05
Other Income	3.10	2.81	1.94	1.76	2.19	D&A	0.58	1.00	0.95	0.99	0.99
Total Revenue	3.10	2.85	2.21	2.43	3.48	NCWC	1.30	0.32	-2.19	-0.38	0.27
Cost of Sales	-	-	-0.05	-0.13	-0.26	Other	-	0.41	-	-	-
R&D	-4.36	-4.46	-4.05	-5.03	-4.83	Operating cash flow	-4.52	-6.14	-5.09	-8.39	-8.32
SG&A	-4.46	-4.52	-5.40	-6.04	-6.44	Payments for PPE	-1.15	-0.79	-0.80	-0.90	-1.00
EBITDA	-5.72	-6.14	-7.29	-8.77	-8.06	Other payments	-	-	-	-	-
D&A	-0.58	-1.00	-0.95	-0.99	-0.99	Proceeds from asset sale	-	-	-	-	-
EBIT	-6.30	-7.14	-8.23	-9.76	-9.05	Investing cash flow	-1.15	-0.79	-0.80	-0.90	-1.00
Net Interest	-0.10	-0.09	-	-	-	Equity raised, net costs	9.41	4.18	4.70	9.40	9.40
NPBT	-6.40	-7.23	-8.23	-9.76	-9.05	Net borrowings	-0.26	1.08	-1.52	-0.18	-
Tax expense	-	-	-	-	-	Lease repayments	-0.18	-0.29	-	-	-
Discontinued operations	-	-	-	-	-	Other	-	-	-	-	-
NPAT	-6.40	-7.23	-8.23	-9.76	-9.05	Financing cash flow	8.97	4.97	3.18	9.22	9.40
Balance Sheet						Investment Fundamentals					
A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e	A\$Ms	FY24a	FY25a	FY26e	FY27e	FY28e
Cash	6.47	4.52	1.81	1.74	1.81	Free cash flow	-5.67	-6.92	-5.89	-9.29	-9.32
Receivables	-	-	-	-	-	Net cash flow	3.30	-1.95	-2.71	-0.07	0.08
Inventory	-	-	-	-	-	Effects of exchange rate	-	-	-	-	-
R&D Incentive Receivable	2.75	2.58	1.76	2.19	2.10	Cash year end	6.47	4.52	1.81	1.74	1.81
Other	0.12	0.09	0.38	0.16	-						
Current assets	9.34	7.20	3.95	4.09	3.92						
Intangibles	0.82	0.60	0.38	0.16	-						
PPE	2.10	2.11	2.18	2.31	2.48						
Other	-	-	-	-	-						
Non-current assets	2.93	2.71	2.57	2.48	2.48						
Total Assets	12.27	9.91	6.52	6.57	6.40						
	-	-	-	-	0.00						
Payables & Accrued Liabilities	2.02	1.20	0.01	0.02	0.03						
Borrowings	0.24	1.58	0.18	-	-						
Lease Liabilities	0.20	0.22	0.20	0.20	0.20						
Other	0.13	0.11	-	-	-						
Current liabilities	2.60	3.11	0.39	0.22	0.23						
Borrowings	0.40	0.12	-	-	-						
Other liability	0.68	0.46	3.45	4.02	3.49						
Non current liabilities	1.08	0.58	3.45	4.02	3.49						
Total Liabilities	3.68	3.69	3.83	4.24	3.72						
Net Assets	8.59	6.22	2.69	2.33	2.68						
	-	-	-	-	0.00						
Contributed Equity	28.90	33.83	38.53	47.93	57.33						
Retained earnings	-20.98	-28.08	-36.32	-46.07	-55.12						
Reserves/Other	0.67	0.47	0.47	0.47	0.47						
Total Equity	8.59	6.22	2.69	2.33	2.68						
Investment Fundamentals						Investment Fundamentals					
	FY24a	FY25a	FY26e	FY27e	FY28e		FY24a	FY25a	FY26e	FY27e	FY28e
Liquidity						Liquidity					
Current Ratio						Current Ratio	3.6	2.3	10.2	18.8	16.7
Quick Ratio						Quick Ratio	1.1	0.9	5.5	10.8	9.0
Solvency						Solvency					
Debt to Equity						Debt to Equity	0.2	0.4	1.4	1.8	1.4
Debt to Assets						Debt to Assets	0.1	0.2	0.6	0.6	0.6
LT Debt to Assets						LT Debt to Assets	0.0	0.0	0.0	0.0	0.0
Profitability						Profitability					
Net Margin						Net Margin	n/a	n/a	n/a	n/a	n/a
ROA						ROA	-52%	-73%	-126%	-149%	-141%
ROE						ROE	-75%	-116%	-307%	-419%	-338%
Valuation						Valuation					
P/E						P/E	n/a	n/a	n/a	n/a	n/a
EV/EBITDA						EV/EBITDA	n/a	n/a	n/a	n/a	n/a
P/B						P/B	0.0	0.0	0.0	0.0	0.0



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