

Wednesday, 26 March 2025

## From Lab to Launch – The Blood Test Changing the Game

Evolution provides an update on BCAL Diagnostics Ltd (“Bcal” or “BDX”), the Australian company pioneering non-invasive breast cancer diagnostics. On Monday, 24 March 2025, BCAL announced the commercial launch of BREASTEST *plus*™, a first-in-class blood test that will initially be used alongside standard-of-care imaging for breast cancer screening. This exciting news falls in-line with the previously announced timeframe of commercialisation by the end of Q1 2025. We maintain our speculative buy recommendation and fair valuation of \$0.236 from the 19 February 2025 initiation of the company.

**R&D to C – Commercialisation Is Finally Here:** with the commercial launch of BREASTEST *plus*™ officially underway, BCAL transitions from an R&D focus to revenue generation. More than 21,000 women in Australia face a breast cancer diagnosis in 2025, many of whom would not have complied with regularly screening. By filling a clear gap in care, BCAL is primed for rapid adoption, and stands ready to reshape how clinicians, patients, and investors alike view the promise of early breast cancer detection. Note that, initially, BREASTEST *plus*™, will be provided alongside a mammogram.

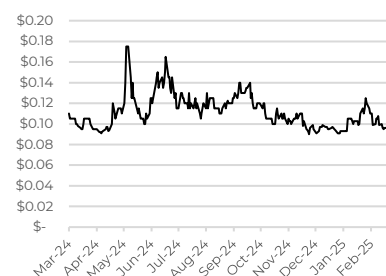
**A New Dawn in Detection:** BCAL Diagnostics is advancing a future where early detection becomes the norm, not the exception. Over 2 million new cases of breast cancer reported globally each year, and 14% of all Australian cancer deaths in women stemming from the disease. Yet roughly half of women aged 50–70 remain unscreened in Australia. There is a pressing need for more accessible and approachable screening. Enter BREASTEST *plus*™: a minimally invasive blood test primed to address low participation rates and deliver a much-needed boost to early diagnosis.

**Quashing Existing Challenges:** mammograms – the current standard-of-care – are unsuitable for nearly 50% of women due their ineffectiveness in detecting cancer in dense breasts. Dense breast tissue appears white on the x-ray image, similar to the appearance of cancers, making it challenging to distinguish between healthy tissue and cancerous lesions. BREASTEST *plus*™ can accurately rule-out breast cancers irrespective of breast tissue density and without the need for manual human interpretation.

**Plenty of Upside:** we maintain a speculative buy recommendation with a fair valuation assessment of \$0.236. Our valuation balances expectations of near-term commercial success and the potential for latency in adoption of new diagnostic technology often seen in this space. We expect BCAL to make strong near-term inroads into the US\$4.96 billion breast cancer diagnostics market.

Share Price	\$0.10
Fair Valuation	\$0.236
Upside (from initiation)	136% (115%)
Recommendation	SPEC BUY
52-Week Range	\$0.185 - \$0.086
Market Cap	~\$36M
Cash	~\$7M
Enterprise Value	~\$29M
Free Float	~63%

### 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.

### Analyst

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Click [here](#) to access Evolution Capital's Initiation Report of BCAL Diagnostics published 19 February 2025.

### Catalyst

First sale of BREASTEST *plus*™ at Sydney Breast Clinic  
BREASTEST *plus*™ commercial rollout – primary focus on NSW & Vic  
National rollout  
Publication in peer reviewed journals  
Updates on BREASTEST® for the US  
Updates on further BREASTEST® products

### Timeline

27 March 2025  
Q2 2025  
H2 2025  
H2 2025  
H2 2025  
FY2026



# 1. Strap Yourselves In Commercialisation Is Here

BCAL has successfully launched BREASTEST *plus*<sup>TM</sup>, an innovative blood test for the screening of breast cancer

BCAL Diagnostics has achieved a significant milestone with the commercial launch of BREASTEST *plus*<sup>TM</sup>, marking a new era in breast cancer diagnostics. This innovative blood test, designed initially to complement standard-of-care imaging in breast cancer screening and diagnostics, is set to revolutionize the field, particularly for women with high breast density.

The company has successfully met its previously announced target of making the test commercially available in Australia by the end of Q1 CY2025. BREASTEST *plus*<sup>TM</sup> will be available at Sydney Breast Clinic from Thursday, 27 March 2025, with a systematic national rollout planned to follow.

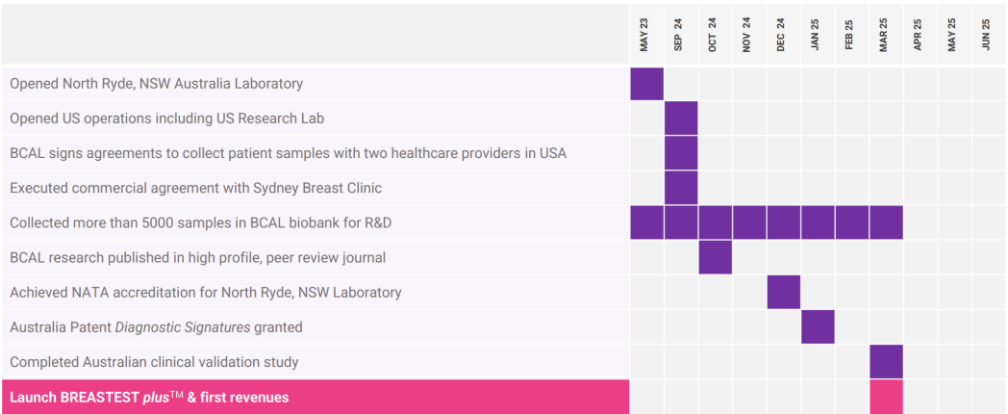


Figure 1: graph outlining the milestones achieved by BCAL on their path to the announcement of commercialisation of BREASTEST *plus*<sup>TM</sup>; sourced from company presentation.

## Initial Rollout and Expansion Plans

Sales will initially start exclusively at long-term partner, Sydney Breast Clinic. This 'soft' launch strategy allows BCAL to attain real-world validation and refine their processes ahead of full commercial launch.

BCAL's commercialisation strategy begins with a focused rollout at Sydney Breast Clinic, a long-standing partner and respected institution in women's health. This initial launch site serves as a crucial proving ground for BREASTEST *plus*<sup>TM</sup>, allowing for real-world validation and refinement of operational processes. The choice of Sydney Breast Clinic as the inaugural commercial site is strategic, leveraging existing relationships and the clinic's reputation to build credibility and drive early adoption.

Following the successful implementation at Sydney Breast Clinic, the company intends to extend availability of the test to additional centres in Sydney and Melbourne, gradually increasing its footprint in Australia's two largest metropolitan areas. This phased approach allows BCAL to carefully manage resources, gather valuable feedback, and optimize the patient experience before scaling up operations.

## The Run Up to Commercialisation

The Company's progress to this pivotal milestone has been marked by key achievements. On December 12, 2024, BCAL secured National Association of Testing Authorities (NATA) accreditation for its laboratory, a crucial step in ensuring the test's reliability and credibility. This accreditation followed extensive clinical validation studies involving over 4,000 blood samples, which yielded excellent results and validated the test's accuracy and efficacy. NATA has now also added BREASTEST *plus*<sup>TM</sup> to its scope of accredited tests, enabling sales to begin.

## Market Potential & Future Outlook

The launch of BREASTEST *plus*<sup>TM</sup> is particularly significant given its potential to address the challenges posed by high breast density, which affects approximately 50% of Australian women participating in breast cancer screening programs. By providing clinicians with an additional tool to overcome this longstanding issue, BCAL is addressing a critical unmet need in breast cancer diagnostics.

*Roughly 50% of Australian women do not participate in the national screening program. One reason is due to mammograms not being suitable for dense breast tissue: cancerous lesions may be hidden by similar looking dense breast tissue.*

As discussed in our initiation report, mammography – the standard-of-care in breast cancer diagnostics – is not suitable for women with dense breasts. On a mammogram, dense tissue appears white, similar to how potential abnormalities like tumours appear, making it challenging to distinguish between healthy dense tissue and cancerous lesions (see figure 1 below). This similarity can obscure tumours, reducing the sensitivity of mammograms and increasing the likelihood of missed cancer detections.

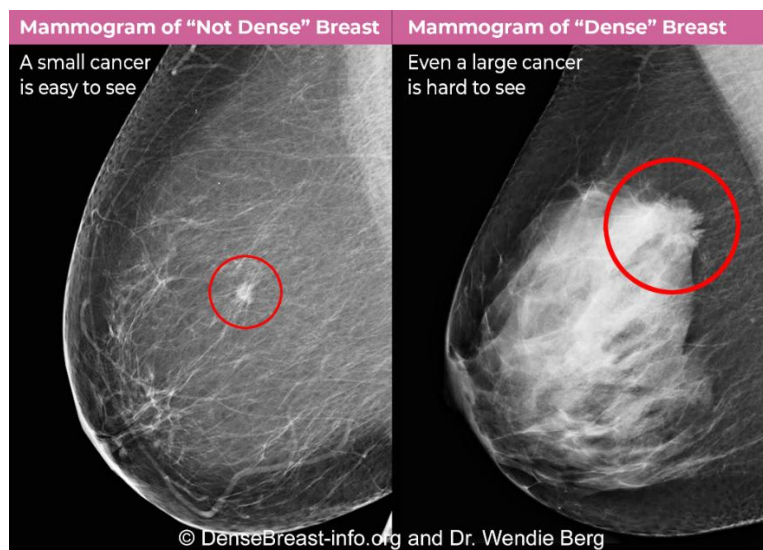


Figure 2: image courtesy of breastcancer.org highlighting the difficulty radiologists face in identifying cancers in patients with dense breasts.

In Australia, approximately 43% of women aged 40 to 74 have dense breasts (defined as category C or D of the four-category scale called BI-RADS: category A represents almost entirely fatty breast tissue with very little fibrous or glandular tissue while category D represents extremely dense breasts made up of a large amount of fibrous and glandular tissue).

On top of this, a mammogram is a highly uncomfortable and painful procedure – a real deterrent for women considering screening. As a refresher, a mammogram involves X-ray imaging of the breast under heavy compression between two plates. Moreover, cancer diagnosis requires interpretation of the image by a radiologist, which can lead to high incidence of false positive and negative results.

*The global breast cancer diagnostics market is valued at approximately US\$4.96 billion, representing a significant opportunity for BCAL.*

With their simple, minimally invasive blood test, the company is well-positioned to capitalize on the US\$4.96 billion global breast cancer diagnostics market. As BCAL generates its first revenue this week, investors can look forward to future growth driven by clinical adoption. The successful commercialization of BREASTEST plus™ marks the beginning of an exciting new chapter for BCAL Diagnostics, with the promise of significant positive impact on women's health and the potential for substantial returns for investors.

## Not a New Story

### 10+ Years of Clinical Development & Validation

While yesterday's announcement represents the start of BCAL's life as a revenue-generating outfit, it's important to reemphasise the Company's strong foundation. Founded in 2010, the company has developed and validated their breast cancer detection technology in-house using over 4,000 blood samples.

BCAL has robustly de-risked its technology through a comprehensive clinical validation program. The journey began with the SENSIBLE studies in Australia – SENSIBLE-1 established the initial feasibility of the lipid biomarker panel, while SENSIBLE-2, with its larger and more diverse cohort, validated the diagnostic performance and refined the algorithm. With SENSIBLE-3 nearing completion, the



*BCAL has de-risked commercial efforts through extensive clinical validation of the product, including testing on over 4,000 blood samples.*

panel is now poised for commercial use, incorporating data from a broad spectrum of patient demographics and clinical settings.

Complementing these domestic efforts, international collaborations have further underscored the test’s reliability: a North Carolina study with Precion Inc. evaluated 656 samples and achieved a sensitivity of 90% and specificity of 85.5%, mirroring the strong outcomes observed in Australia, while European studies confirmed clinical utility with a sensitivity of 91%, specificity of 79%, and an impressive AUC of 0.95.

These studies feature key collaborations with leading experts in the breast cancer field, firmly establishing BREASTEST *plus*™ as a reliable, globally applicable diagnostic tool that stands on a solid foundation.

2. Valuation

We maintain a speculative buy recommendation on BCAL. There is no change to our fair valuation of A\$0.236. Central to this valuation is our revenue forecasting model, which remains underpinned by the company’s demonstrated ability to execute on its stated commercialisation timeline. Our original revenue assumptions – which project a gradual but meaningful adoption curve driven by the test’s modest price point, partnership strategy, and strong clinical validation data – continue to hold true.

Critically, commercialisation being in-line with initial guidance has effectively de-risked our near-term revenue estimates. We continue to expect a robust uptake in clinical settings from FY26, accelerated by the test’s impressive diagnostic metrics, while still applying conservative penetration rates to reflect the measured pace of market adoption common in the healthcare diagnostics sector.

BDX Valuation (A\$M)	
Terminal Growth Rate	6%
Discount Rate	10.42%
Terminal Value (TV)	198.86
Present Value of TV	109.71
Enterprise Value	90.14
Net Debt	-12.90
Equity Value	103.05
Fully Diluted Shares	436.17
Fair Valuation	\$0.236

Figure 3: DCF-derived valuation of BDX remains unchanged.

### 3. Key Risks

**Clinical & Regulatory Risk:** BCAL's lead diagnostic, BREASTEST®, must continue to demonstrate strong clinical performance across further trials and validation studies. Any delay or setback—such as insufficient efficacy data, safety concerns, or unanticipated challenges in meeting regulatory standards—may slow down or halt product approvals. This situation could limit the company's ability to commercialise and ultimately impact revenue projections.

**Commercialisation & Market Adoption:** While BCAL anticipates robust demand for a minimally invasive blood-based test, adoption ultimately depends on clinicians' willingness to replace or supplement existing breast cancer screening methods. Hesitancy from medical practitioners, uncertainty around clinical guidelines, or reluctance from imaging centres could prolong the timeline for widespread uptake, affecting projected revenues.

**Competition & Technological Obsolescence:** The breast cancer diagnostics space is highly competitive and evolving quickly. Established market leaders and emerging technologies (such as advanced imaging or alternative biomarker panels) may gain an edge if they prove faster, cheaper, or more accurate. BCAL must consistently refine and update its diagnostic panel to maintain differentiation.

**Reimbursement & Pricing Pressures:** Securing sustainable reimbursement is essential to attain broad-based adoption, particularly as it pertains to US commercialisation. Even with regulatory clearance, there is a risk that payors could deny coverage or set rates that undermine profitability. Extended negotiations or delays in obtaining reimbursement approvals may limit market reach and erode projected earnings.

**Manufacturing & Supply Chain Reliability:** As BCAL scales up, the company's operational capacity, including laboratory processing and logistical efficiencies, must expand without compromising quality. Supply chain interruptions, equipment failures, or sample processing errors can lead to backlogs and negatively impact customer confidence.

**Financial & Funding Risk:** Research, commercial expansion, and regulatory filings require substantial capital. Underperformance in revenue or shifts in market sentiment could restrict BCAL's ability to raise additional funds on favourable terms. Any material shortfall in capital at critical junctures might force the company to modify or delay strategic initiatives.

**Data Security & Privacy:** Collecting and processing sensitive health information poses inherent risks. A cybersecurity breach or failure to comply with privacy regulations could result in reputational damage, financial penalties, and diminished trust among healthcare stakeholders.

**Intellectual Property Protection:** BCAL's unique lipid biomarker signature underpins BREASTEST®'s diagnostic advantage. If proprietary methods or pending patents are challenged, or if rival technologies circumvent BCAL's claims, the company could lose its competitive edge. Ongoing monitoring of the IP landscape, vigilant patent defence, and continuous R&D investment are integral to maintaining long-term differentiation.

## 4. Appendix

### Financial Forecasts

Income Statement							
AS\$M	FY24a	FY25e	FY26e	FY27e	FY28e	FY29e	FY30e
Revenue	0.00	0.35	1.61	3.48	6.77	13.29	22.22
Other Income	3.10	3.09	3.16	3.38	3.60	3.70	3.88
<b>Total Revenue</b>	<b>3.10</b>	<b>3.43</b>	<b>4.76</b>	<b>6.87</b>	<b>10.36</b>	<b>16.99</b>	<b>26.10</b>
Operating expenses	-8.82	-8.78	-8.98	-9.63	-10.23	-10.53	-11.03
<b>EBITDA</b>	<b>-5.72</b>	<b>-5.35</b>	<b>-4.22</b>	<b>-2.77</b>	<b>0.13</b>	<b>6.46</b>	<b>15.06</b>
D&A	-0.58	-0.53	-0.60	-0.67	-0.96	-0.96	-0.96
<b>EBIT</b>	<b>-6.30</b>	<b>-5.88</b>	<b>-4.82</b>	<b>-3.44</b>	<b>-0.83</b>	<b>5.50</b>	<b>14.11</b>
Net Interest	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10
<b>NPBT</b>	<b>-6.40</b>	<b>-5.98</b>	<b>-4.92</b>	<b>-3.54</b>	<b>-0.93</b>	<b>5.40</b>	<b>14.01</b>
Tax expense	0.00	0.00	0.00	0.00	0.00	-1.62	-4.20
<b>NPAT</b>	<b>-6.40</b>	<b>-5.98</b>	<b>-4.92</b>	<b>-3.54</b>	<b>-0.93</b>	<b>3.78</b>	<b>9.80</b>
Weighted Avg Shares Out	246.23	347.98	406.66	432.18	432.70	434.43	436.17

Balance Sheet							
AS\$M	FY24a	FY25e	FY26e	FY27e	FY28e	FY29e	FY30e
Cash	6.47	6.84	6.43	3.44	0.99	4.18	12.47
Receivables	2.86	2.40	2.38	2.23	2.59	4.25	6.52
Other	0.00	0.50	0.75	0.75	0.75	0.80	0.90
<b>Current assets</b>	<b>9.34</b>	<b>9.75</b>	<b>9.56</b>	<b>6.42</b>	<b>4.33</b>	<b>9.23</b>	<b>19.90</b>
PPE	2.10	2.17	2.17	2.10	3.24	2.38	1.53
Intangible assets and Other	0.82	0.54	0.55	0.63	1.43	1.90	2.65
<b>Non-current assets</b>	<b>2.93</b>	<b>2.71</b>	<b>2.72</b>	<b>2.73</b>	<b>4.67</b>	<b>4.28</b>	<b>4.18</b>
<b>Total assets</b>	<b>12.27</b>	<b>12.46</b>	<b>12.28</b>	<b>9.15</b>	<b>9.01</b>	<b>13.51</b>	<b>24.08</b>
Trade and other payables	2.02	2.02	2.07	2.22	2.35	2.42	2.54
Borrowings	0.24	0.25	0.14	0.00	0.00	0.00	0.00
Other	0.33	0.18	0.16	0.13	0.11	0.08	0.06
<b>Current liabilities</b>	<b>2.60</b>	<b>2.45</b>	<b>2.36</b>	<b>2.35</b>	<b>2.46</b>	<b>2.50</b>	<b>2.59</b>
Borrowings	0.40	0.14	0.00	0.00	0.00	0.00	0.00
Other liability	0.68	0.54	0.47	0.39	0.32	0.24	0.17
<b>Non current liabilities</b>	<b>1.08</b>	<b>0.68</b>	<b>0.47</b>	<b>0.39</b>	<b>0.32</b>	<b>0.24</b>	<b>0.17</b>
<b>Total Liabilities</b>	<b>3.68</b>	<b>3.14</b>	<b>2.83</b>	<b>2.74</b>	<b>2.78</b>	<b>2.75</b>	<b>2.76</b>
<b>Net Assets</b>	<b>8.59</b>	<b>9.32</b>	<b>9.45</b>	<b>6.41</b>	<b>6.23</b>	<b>10.76</b>	<b>21.32</b>
Contributed Equity	28.90	35.36	40.16	40.37	40.37	40.57	40.57
Retained earnings	-20.98	-26.96	-31.88	-35.42	-36.35	-32.57	-22.77
Reserves/Other	0.67	0.92	1.17	1.46	2.21	2.76	3.51
<b>Total equity</b>	<b>8.59</b>	<b>9.32</b>	<b>9.45</b>	<b>6.41</b>	<b>6.23</b>	<b>10.76</b>	<b>21.32</b>

Statement of Cashflows							
AS\$M	FY24a	FY25e	FY26e	FY27e	FY28e	FY29e	FY30e
Net profit for period	-6.40	-5.98	-4.92	-3.54	-0.93	3.78	9.80
Depreciation & Amortisation	-0.58	-0.53	-0.60	-0.67	-0.96	-0.96	-0.96
Changes in working capital	-0.26	-0.11	0.14	-0.17	0.47	1.75	2.47
Other	-1.04	0.00	0.00	0.00	0.00	0.00	0.00
<b>Operating cash flow</b>	<b>-4.52</b>	<b>-5.34</b>	<b>-4.46</b>	<b>-2.70</b>	<b>-0.44</b>	<b>2.99</b>	<b>8.29</b>
Payments for PPE	-1.15	-0.50	-0.50	-0.50	-2.00	0.00	0.00
Acquisition payments	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Other	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>Investing cash flow</b>	<b>-1.15</b>	<b>-0.50</b>	<b>-0.50</b>	<b>-0.50</b>	<b>-2.00</b>	<b>0.00</b>	<b>0.00</b>
Equity Raised	9.57	6.74	5.00	0.21	0.00	0.20	0.00
Borrowings	-0.26	-0.25	-0.25	0.00	0.00	0.00	0.00
Other	-0.34	-0.27	-0.20	0.00	0.00	0.00	0.00
<b>Financing cash flow</b>	<b>8.97</b>	<b>6.21</b>	<b>4.55</b>	<b>0.21</b>	<b>0.00</b>	<b>0.20</b>	<b>0.00</b>
<b>Cash flows</b>	<b>3.30</b>	<b>0.37</b>	<b>-0.41</b>	<b>-2.99</b>	<b>-2.44</b>	<b>3.18</b>	<b>8.29</b>
<b>Cash year end</b>	<b>6.47</b>	<b>6.84</b>	<b>6.43</b>	<b>3.44</b>	<b>0.99</b>	<b>4.18</b>	<b>12.47</b>

Investment Fundamentals							
	FY24a	FY25e	FY26e	FY27e	FY28e	FY29e	FY30e
Growth							
Revenue Growth %	na	n/a	361%	117%	94%	96%	67%
EBITDA Growth %	na	n/a	n/a	n/a	n/a	5065%	233%
NPAT Growth %	na	n/a	n/a	n/a	n/a	n/a	259%
Margins & Ratios							
Quick Ratio	3.6	3.8	3.7	2.4	1.5	3.4	7.3
Debt to Equity	0.02	0.01	n/a	n/a	n/a	n/a	n/a
Net Margin	n/a	n/a	n/a	n/a	n/a	22.2%	37.6%
ROA	n/a	n/a	n/a	n/a	n/a	28.0%	40.7%
ROE	n/a	n/a	n/a	n/a	n/a	9.3%	24.2%
Valuation							
EPS	n/a	n/a	n/a	n/a	n/a	0.01	0.02
FCF per share	n/a	n/a	n/a	n/a	n/a	0.01	0.02

## Leadership Team

### Jayne Shaw

Co-Founder & Executive Chair

Jayne Shaw is the Executive Chair and co-founder of BCAL Diagnostics. She is a qualified and registered nurse in the UK, and on arrival in Australia she became Director of Nursing and Chief Executive Officer of two private hospitals. Founding a consulting business, later acquired by Healthsouth, she co-founded Vision Group—an ASX-listed Ophthalmic Doctor equity model. With diverse roles on private healthcare boards, she co-owns Sydney Breast Clinic. Holding current board positions at The Citadel Group, Ellerston JAADE Australian Private Assets Fund, Mable Technologies, and Corum Group. Jayne also serves as a Non-Executive Director at Pinnacle Charitable Foundation and Prosperion.

### The Hon Ron Phillips

Co-Founder

After 15 years in the NSW Parliament, including roles as Minister for Health and Deputy Leader of the Opposition, Ron forged a thriving consulting business in Health and Aged Care. Formerly co-owner and Managing Director of Sydney Breast Clinic, later sold to Healthscope, he now chairs the Sydney Local Health District and serves as Director on Westmead IVF.

### David Darling

NED

David Darling is a highly credentialed leader and executive who brings a wealth of commercial experience to BCAL from his prior role as CEO of Pacific Edge, a NZX50 and ASX listed business focused on commercialising its bladder cancer diagnostics tests across global markets, with commercial operations in New Zealand, Australia, Singapore and the USA. Prior to Pacific Edge, Mr Darling held senior management positions with Fletcher Challenge.

Mr Darling has a background as a scientist with a specialty in genetics and has more than three decades of experience in developing and commercialising life sciences and biotechnology products.





<b>Mark Burrows AO</b> Independent NED	Mark Burrows AO, with a distinguished global career in investment banking, transitioned into advocating private sector engagement for sustainable development and green finance evolution. Mark held senior advisory roles with UNEP, UNDP, The Green Finance Initiative in London, and the G20 Sustainability Group. Presently, he serves on the Asian Board of the Nature Conservancy, embodying his commitment to environmental initiatives and sustainable practices.
<b>Jonathan Trollip</b> Independent NED	Jonathan, an Independent Non-Executive Director, brings over 30 years of global expertise in commercial, corporate governance, and law. He currently chairs ASX-listed entities, including Global Value Fund Ltd, Plato Income Maximizer Limited, and Spheria Emerging Companies Limited. Jonathan serves as a non-executive director for Kore Potash Limited on LSE, JSE, and ASX. His extensive background includes leadership roles at Meridian International Capital Limited and Herbert Smith Freehills. A Fellow of the Australian Institute of Company Directors, he previously chaired Future Generation Investment Company Ltd, Antipodes Global Investment Company Ltd, and Spicers Limited.
<b>Dr John Hurrell</b> NED & Consultant	Dr Hurrell has developed and successfully commercialised multiple products and services in life sciences and diagnostics over a career in the industry spanning more than 35 years. He has developed and managed start-up and early-stage companies including successful life science companies based on university developed technologies. Most notably Dr Hurrell spent almost 7 years in managerial and executive roles with NYSE-listed, Fortune 500 clinical laboratory company Quest Diagnostics. Within Quest's subsidiary Focus Diagnostics, he led the development and launch of more than 70 molecular diagnostics tests and successfully gained 510(k) approvals for 6 products. He also served as VP of Business Development at Quest Diagnostics.

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