EVOLUTION CAPITAL

ASX: BDX

Initiation Report

February 19th, 2025

Revolutionising Breast Cancer Screening

We initiate coverage on BCAL Diagnostics Limited ("BCAL") with a fair valuation of A$0.236, representing approximately 114% expected upside from the last closing share price of A$0.11. BCAL Diagnostics is an Australian company pioneering a blood test for the early detection of breast cancer called BREASTEST®. Designed to initially complement traditional imaging methods like mammography, this innovative test offers an accurate means of identifying breast cancer, independent of breast tissue density. With over two million new cases of breast cancer diagnosed annually worldwide, BCAL aims to address current screening hindrances by improving accessibility, accuracy, and patient outcomes for women. The company has made significant progress in commercialising BREASTEST®, including achieving NATA accreditation for its laboratory, achieving excellent results across extensive clinical validation studies, and preparing for a phased market launch starting in the current quarter.

What Matters Most

Commercial Launch of BREASTEST® Imminent: BCAL is set to launch BREASTEST® in Q1 2025, with Sydney Breast Clinic as the first commercial site. Q1 will see first revenues from sale of the product. With established partnerships with industry-leading clinics and hospitals, BCAL is primed to drive commercial scale and adoption in a US$4.96 billion global breast cancer diagnostics market.

Superiority Over The Current Standard of Care: Mammography is ridden with limitations: it is highly uncomfortable for the patient which results in low testing rates amongst eligible populations; diagnosis requires interpretation of the X-ray image by a radiologist, which can lead to high incidence of false positive and negative results; and it is not suitable for women with dense breasts (approximately half of the population in Australia, and an even greater proportion in parts of Asia). Yet in the US, over 40 million mammograms are performed per year. BREASTEST® is a simple test that involves a minimally invasive and quick blood collection (which everyone has done during their lifetime). Applying an algorithm developed using machine learning on over 4,000 blood samples, BREASTEST® accurately identifies breast cancers without the need for manual human interpretation, and no matter the breast density of the patient.

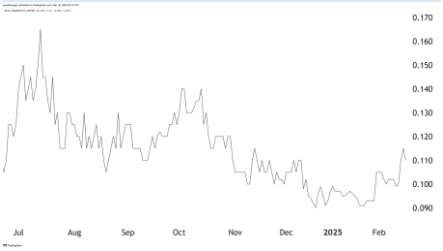
Breast Cancer: over 2 million new cases of breast cancer are diagnosed globally per year. Over 600,000 women die annually. In Australia, 14% of all cancer deaths in women are due to breast cancer, yet 52% of Australian women aged 50 to 70 are unscreened (approximately 2 million women). While on average 100% of women diagnosed at stage 1 breast cancer survive five years on from diagnosis, this figure is 32% at stage 4 diagnosis. Facilitating early diagnosis is therefore paramount to achieving positive patient outcomes.

Valuation: We value BDX at A$0.236 per share in a base-case scenario, incorporating conservative assumptions on the company's ability to tap into the sizeable breast cancer screening market in the near term. This valuation considers latent adoption of this new technology by diagnostic service providers and clinicians, while also factoring in potential market penetration by competitors. Future expenses required to grow and further capital raising initiatives are considered.

BCAL diagnostics

Share Price	A$0.11
Fair Valuation	A$0.236
52-Week Range	A$0.085 – A$0.185
Market Cap	~A$37.5m
Cash	~A$7.05m
Enterprise Value	~A$32.6m
Free Float	~63.2%

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.

Top 5 Shareholders

Capital Property Corp	11.2%
Jayne Shaw	9.00%
Mera Vale	6.97%
Ron Phillips	6.07%
Netwealth Investments	3.1%

Analyst

Jacob Hoenig jh@eveq.com

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Investment Case

BCAL Diagnostics represents a compelling investment opportunity due to its innovative, minimally invasive approach to breast cancer detection and its strong commercial positioning. Traditional screening methods, particularly mammography, have well-documented limitations, including discomfort, accessibility issues, and inefficacy in women with dense breast tissue. BCAL's BREASTEST® blood test, backed by rigorous clinical validation from over 4,000 samples, offers a highly sensitive and specific approach, filling a critical gap in early detection. With NATA accreditation in place, BCAL is now finalizing the necessary analytical and clinical validation of BREASTEST®. Once validation is successfully completed, BCAL will request NATA to add BREASTEST® to its scope of accredited tests. BCAL is poised to launch commercially in Q1 2025, with Sydney Breast Clinic, a long-standing partner, as its first launch site.

The company's lipidomics-based approach sets it apart from competitors employing Circulating Tumour DNA (ctDNA) or Circulating Tumour Cells (CTC) for example, offering class leading sensitivity and Negative Predictive Value to enable physicians to accurately rule out those who do not have breast cancer. Given the immense size of the global breast cancer diagnostics market (US$4.96 billion), even conservative adoption rates present a significant revenue opportunity. BCAL's strategic roadmap includes expansion into the US, where partnerships with research centres and clinicians are already in place. Additionally, the pursuit of Medicare Benefits Schedule (MBS) listing in Australia would unlock immeasurable scale.

Our valuation of the company, at A$0.236 per share representing a 114% potential upside, is supported by a disciplined financial strategy that limits capital expenditure while enabling scalable growth. With a robust intellectual property portfolio spanning multiple jurisdictions and an experienced governance and executive team with a proven track record in diagnostics and commercialisation, BCAL is positioned to establish a dominant foothold in the industry. While regulatory and competitive risks exist, BCAL's strategic de-risking approach – through partnerships, financial prudence, and regulatory navigation – ensures resilience. Through critical analysis of the company, market, competition, and regulatory requirements, we believe BCAL presents a compelling case for investors seeking exposure to a transformative healthcare innovation.

BREASTEST

A Modern Screening Solution for Breast Cancer

BREASTEST®: BCAL has developed an innovative blood test to screen for breast cancer.

BREASTEST® is an innovative, non-invasive blood test developed by BCAL Diagnostics for the early detection of breast cancer. It utilizes a proprietary lipidomic signature identified through advanced machine learning algorithms to distinguish between healthy individuals and those with breast cancer. Put simply, the levels of specific lipid biomarkers in blood plasma are analysed by Liquid Chromatography Mass Spectroscopy (LCMS) in the company's commercial laboratory, to determine whether the results fit a machine learning-derived 'cancer signature'. This technology was developed over a decade of research and has been validated in multiple domestic and international studies. The test is initially designed to complement current imaging

technologies like mammograms, targeting all women regardless of age, breast tissue density, or location.

Clinical Validation

BREASTEST® has been developed and validated using over 4,000 blood samples.

BCAL's clinical validation program for BREASTEST® has involved several clinical studies to ensure the test's reliability and accuracy. The "SENSIBLE" studies, conducted in Australia, have been a significant component of this evaluation and validation processes. SENSIBLE-1 was designed to assess the initial feasibility of the lipid biomarker panel in differentiating breast cancer patients from healthy controls. This study analysed a cohort of Australian samples and yielded strong preliminary results, providing the foundation for further refinement of the lipid signature. SENSIBLE-2 built upon these findings with a larger, more diverse cohort. This study aimed to validate the panel's diagnostic performance and refine the diagnostic algorithm. Results demonstrated excellent diagnostic metrics, solidifying the panel's robustness and guiding the inclusion criteria for the final test design. SENSIBLE-3, currently nearing completion focuses on finalizing the lipid panel and optimizing the diagnostic algorithm for commercial use. This study incorporates additional performance evidence, leveraging a cohort of patients recruited in Australia. These patients represent various patient demographics and clinical presentations. It aims to ensure the test's applicability across various patient populations and clinical settings.

In addition to the SENSIBLE studies, BCAL conducted an international study in collaboration with Precion Inc. in North Carolina, USA. This study analyzed 656 samples, including 390 from breast cancer patients and 266 from healthy controls. The results showed a sensitivity of 90% and a specificity of 85.5%, which aligned closely with findings from the Australian studies. This consistency across populations highlights the reproducibility and transferability of BREASTEST®, affirming its potential for global application.

BREASTEST® uses a proprietary 20-lipid signature derived from machine learning to identify cancerous results.

Further data was derived from European cohorts, where the validation efforts identified a specific 20-lipid blood signature associated with breast cancer. The European study demonstrated a sensitivity of 91% and specificity of 79%, with an AUC of 0.95, underscoring the test's performance.

Additionally, BCAL has partnered with the KIMS Institute and Indo American Hospital in Hyderabad, India, to conduct a feasibility study to evaluate BREASTEST® in an Indian population. This initiative aims to ensure the test's performance across diverse genetic and demographic profiles, further enhancing its global applicability.

Accreditation

BCAL has received NATA accreditation for their laboratory and will soon be accredited to provide BREASTEST®.

The National Association of Testing Authorities (NATA) is Australia's recognized national accreditation authority for analytical laboratories and testing service providers. NATA accreditation ensures that laboratories meet international standards for technical competence and quality management, specifically ISO 15189 for medical laboratories. This accreditation is crucial for laboratories seeking to provide reliable and internationally recognized testing services.

BCAL obtained NATA accreditation for their North Ryde laboratory in December 2024. This enables BCAL's laboratory to endorse specific test reports with NATA's logo,

providing assurance of reliability to clinicians and patients. Moreover, NATA accreditation facilitates acceptance of these test results both nationally and internationally.

With NATA accreditation in place, BCAL is now finalizing the necessary analytical and clinical validation of BREASTEST®. Once validation is successfully completed, BCAL will request NATA to add BREASTEST® to its scope of accredited tests.

Commercial Launch

BCAL is expecting to begin sales in Q1 CY25, with an initial launch at SBC.

BCAL is poised to introduce BREASTEST® in Australia during the first quarter of the 2025 calendar year. The initial rollout will commence with a soft launch at the Sydney Breast Clinic (SBC), allowing for the refinement of operational processes and the incorporation of feedback from both clinicians and patients. This phased approach is designed to ensure a seamless integration into existing healthcare frameworks, with the objective of expanding availability nationwide thereafter.

Figure 1: BCAL is working with clinicians from leading centres around Australia and globally

Patient Journey

The collection procedure is designed to be straightforward and patient-friendly:

As with conventional blood sample collections, the process is minimally invasive for the patient, and very simple.

1. Referral: a healthcare provider provides a referral for BREASTEST® based on individual risk factors or as part of routine screening.
2. Sample Collection: a blood sample is drawn at a certified collection centre.
3. Laboratory Analysis: the sample is sent to Bcal's accredited laboratory, where sample processing and analysis is conducted to detect the specific lipid biomarker signature associated with breast cancer.
4. Results Reporting: findings are communicated to the referring clinician who discusses the results and any necessary follow-up actions with the patient.

This minimally invasive process aims to enhance patient comfort and encourage higher participation rates in breast cancer screening programs.

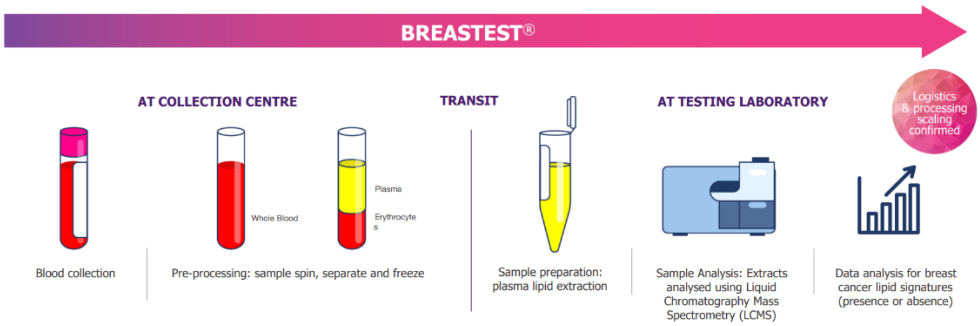

Figure 2: Visual Depiction of the collection and analysis process for BREASTEST

Cost

BCAL has conducted independent research and focus groups to determine a patient-centric pricing model for the test for its initial soft launch. The proposed cost to patients is expected to be approximately A$300 per test and will be provided alongside a mammogram. This pricing strategy is intended to make the test accessible to a broad demographic, thereby promoting early detection and improving patient outcomes.

Operational Capacity

Bcal's North Ryde, NSW lab has capacity to process 20,000 tests annually.

BCAL has conducted independent research and focus groups to determine a patient-centric pricing model for the test for its initial soft launch. The proposed cost is approximately A$300 per test and will be provided alongside a mammogram. This pricing strategy is intended to make the test accessible to a broad demographic, thereby promoting early detection and improving patient outcomes.

Intellectual Property Portfolio

BCAL has established a robust intellectual property (IP) portfolio to safeguard its innovative breast cancer detection technology. This portfolio encompasses patents, trademarks, and proprietary methodologies, ensuring the company's competitive edge in the diagnostic market.

Patents

As of 2024, BCAL's IP portfolio includes the brand, logo trademark registrations and the granting of its patent across eight key jurisdictions, including Europe, the United States, and Canada. These patent grants cover critical aspects of the technology and methods that constitute BREASTEST®, providing comprehensive protection for the company's innovations.

The company continues to prosecute two BCAL-owned patent families closely aligned with the technology and methods integral to BREASTEST®. Accelerated examination of one of these patents in Australia is anticipated to lead to the first BCAL-owned patent grant, reinforcing the company's IP position ahead of the Australian product launch.

Trademarks

BCAL has secured Australian trademark registration for the name of its flagship product, BREASTEST®. Trademark applications are also pending in strategic global markets, including the United States, United Kingdom, Europe, China, India, Canada,

South Korea, and New Zealand. These registrations are crucial for brand recognition and protection as BCAL expands its market presence internationally.

Strategic Importance

A strong IP portfolio is vital for BCAL's commercial strategy, providing a competitive advantage and creating barriers to entry for potential competitors. By securing patents and trademarks in major markets, BCAL not only protects its technological innovations but also enhances its appeal to investors and partners, facilitating global expansion and adoption of BREASTEST®.

Breast Cancer

An Overview

Anatomy

Breast cancer is a disease in which malignant (also known as 'cancer') cells form in the tissues of the breast. In essence, abnormal cells grow in an uncontrolled way to form a tumour.

The breast is made up of lobes and ducts. Each lobe has many smaller sections called lobules. Lobules end in dozens of tiny bulbs. The lobes, lobules, and bulbs are connected by thin tubes called ducts which carry milk to the nipple. Breast tissue extends from the collarbone to the lower ribs, sternum, and armpit.

Each breast also has blood vessels and lymph vessels. The lymph vessels carry lymph fluid between lymph nodes, which are small bean-shaped structures that store white blood cells that help in the body's immune response to fight infection and disease. Everyone has a different number of lymph nodes, and they are located in the armpit, under the breastbone, or in the neck. The lymph nodes in the armpit, which are closest to the breasts, drain lymph fluid away from the breast. This means they are often the first place where breast cancer cells spread throughout the body.

Cancer Formation

Tumours form when cells grow in an abnormal manner, forming a mass. Some tumours are harmless ('benign'), some invade surrounding tissue ('malignant' or 'cancerous').

To understand how cancer can originate, it can be helpful to understand how regular cells function. The body is constantly making new cells to replace worn out tissue or to heal injuries. Healthy cells replicate and grow in a controlled manner. Sometimes cells keep growing in an abnormal way, and as they grow, they form a mass called a tumour. Not all tumours are cancerous: some are benign – where they grow slowly and do not invade surrounding tissue or other parts of the body – but some are malignant and have the potential to invade surrounding tissue and spread to other parts of the body.

Breast cancer forms when malignant cells grow abnormally. Once this occurs, the malignant cells may begin to invade surrounding tissues, breaking through the normal boundaries that keep cells confined to their original locations. This invasive action allows cancer cells to infiltrate nearby structures such as the ducts lobules, and other adjacent tissues. At this stage, the condition becomes a problem as it interferes with the normal function of these tissues and organs.

Cancer can spread (also known as "metastasize") through the body via the lymphatic system or through the bloodstream. When cancer cells enter the lymph vessels, they

Metastasizing is when the cancer spreads through the lymphatic system or bloodstream to other parts of the body.

can spread to lymph nodes and potentially establish secondary tumours there. Similarly, when cancer cells invade blood vessels, they can circulate throughout the body to various organs and structures including the liver, lungs, bones, and the brain.

The ability of cancer to metastasize significantly worsens the prognosis because it leads to the development of tumours in vital organs. Common consequences include pain, organ failure, and significant deterioration in overall health. Early detection and treatment are crucial in preventing cancer from reaching this advanced stage, as localized tumours are typically much more manageable than metastatic cancer.

Types of Breast Cancer

Breast cancer can be categorised into several types based on its location in the breast and its behaviour. Here are some of the primary types:

- Ductal Carcinoma in Situ (DCIS): A non-invasive cancer where abnormal cells are found in the lining of a breast duct but have not spread outside the duct.
- Invasive Ductal Carcinoma (IDC): The most common type of breast cancer, beginning in the ducts and invading the surrounding breast tissue. It can also spread to other parts of the body.
- Triple-Negative Breast Cancer: A subtype that does not have any of the three common receptors (estrogen, progesterone, or HER2) that are targeted in most treatments, making it more challenging to treat.
- HER2-Positive Breast Cancer: Involves overexpression of the HER2 protein, which promotes cancer cell growth.

The Leading Cause of Death in Women

According to the Australian Institute of Health and Welfare, an estimated 21,000 women were diagnosed with breast cancer in 2024 in Australia. This is around 28% of the estimated cancers diagnosed in women, making it a highly prevalent form of cancer. It is the second most diagnosed cancer in Australia for people aged 20 to 39 and 60 to 79, and the most diagnosed cancer for people aged 40 to 59. To put it in perspective, the risk of being diagnosed with breast cancer over a lifetime is 1 in 7.

Breast cancer incidence has risen in recent years. It is the deadliest cancer for women in Australia.

Breast cancer incidence has increased from 134 cases per 100,000 women in 2000 to 149 cases per 100,000 women in 2024. This increase is partly due to the increased occurrence of breast cancer screening, permitting detection where a cancer may previously have gone undetected.

It is estimated that approximately 3,300 women died from breast cancer in 2024. And according to Breast Cancer Network Australia, around 14% of all cancer deaths in Australian women are breast cancer. Yet 52% of Australian women aged 50-70 are ‘unscreened’. Clearly, there is a need for a screening tool that is more accessible and convenient. This is supported by modelling which suggests annual screening would reduce mortality rates by 40% for women between 40 and 79 years of age.

Looking at breast cancer in a global setting, over 2.1m newly diagnosed female breast cancer cases were reported in 2018. Over 600,000 women die annually from breast cancer.

High Survival Rate When Detected Early

Diagnostic measures have improved over the last few decades, facilitating a greatly improved chances of survival: the five-year survival rate in Australia increased from 78% in 1990-1994 to 92% in 2016-2020.

The chance of survival is far higher when breast cancer is diagnosed in early-stage disease. When diagnosis occurs in stage 4, the probability of survival 5 years on is only 32%.

However, this doesn't tell the full story. According to the National Breast Cancer Foundation, the five-year survival rate decreases significantly the later a breast cancer is identified. The five-year survival rate for Stage 1 (early) breast cancer is, on average, 100% and Stage 2 is 95%. For locally advanced cancers (known as Stage 3) the survival rate is 81%, while the five-year survival rate for Stage 4 (metastatic breast cancer) is significantly lower at 32%.

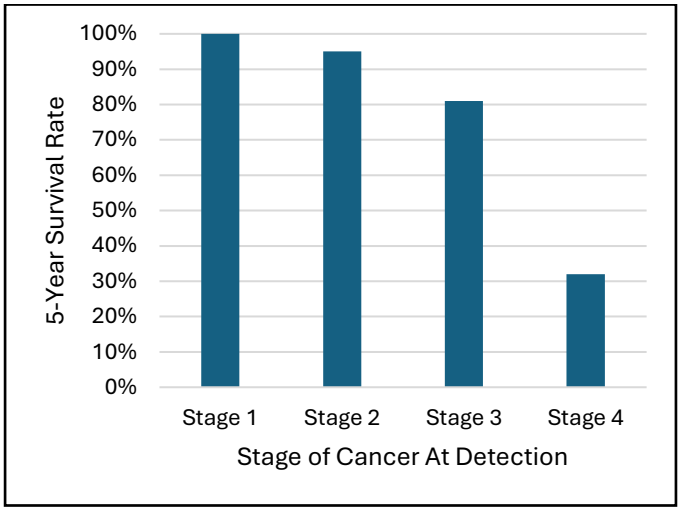

Figure 3: graph displaying the 5-year survival rate for patients across the distribution of diagnosis timing from stage 1 to stage 4

The most recent statistics on the distribution of breast cancer diagnosis by stage are based on 2011 data: 43% in stage 1, 34.7% in stage 2, 12.1% in stage 3, 4.6% in stage 4, and an unknown stage determination for 5.5% of those diagnosed.

Extrapolating this data, we find that approximately 92% of those who are diagnosed with breast cancer survive after five years (excludes the group where diagnosis is at an unknown stage). In short, when breast cancer is diagnosed, patients have a high likelihood of survival. However, there is a great need to make screening more accessible to facilitate early diagnosis.

BCAL's BREASTEST®, through its accuracy and ease of accessibility, will facilitate the early detection of breast cancers when used in scale for a population.

Screening Breast Cancer

From Consultation to Diagnosis: The Process

It must be noted that the patient journey and associated costs and wait times between steps to diagnosis varies across healthcare settings. In Australia, one may seek care exclusively through the public health system free of charge, though typically

this route incurs significant time delay compared to a private breast cancer assessment clinic such as Sydney Breast Clinic, where the time from initial consultation to diagnosis is the same day.

The BreastScreen Australia Program is an additional option provided to women and is a common screening pathway adopted by the Australian population.

BreastScreen Australia Program

The BreastScreen Australia Program is a joint initiative of the federal, state, and territory governments to reduce illness and death from breast cancer. It provides access to a free (Medicare-covered) mammogram every two years for women above the age of forty.

The BreastScreen Australia Program provides women aged 40 and over a free mammogram every 2 years.

Eligible women receive a letter inviting them to attend a screening at a BreastScreen clinic. There are over 750 locations nationwide including permanent clinics, assessment centres, and mobile units. These facilities are distributed across all states and territories. After a mammogram is performed, results are usually sent within two weeks.

Under the program, approximately 1 million mammograms are performed annually. The annual cost is in the range of tens of millions of dollars, though the exact current figures are not made available to the public.

Certain breast cancers metastasize within 2 years, meaning that routine screening only every 2 years may be insufficient in frequency.

Through the provision of this service, it is evident Australian governing bodies are committed to breast cancer monitoring. However, the two-year gap between mammograms creates a need for interim monitoring: HER2+ and Triple-Negative Brest Cancers (collectively representing 25-35% of all breast cancers diagnosed) tend to be aggressive, with a higher likelihood of early metastasis. In these cases, metastasis may occur within two to three years from onset of disease. Moreover, the overall participation rate of the program is around 50%. In other words, half of those who are eligible are not having a mammogram done.

To increase the patient-side participation in breast cancer screening, and to facilitate earlier-stage diagnosis where cancer is present, the BreastScreen Australia Program must be improved upon. The provision of BREASTEST® free-of-charge once annually, for example, would likely greatly increase accessibility, participation in the program, while also reducing the cost burden on the healthcare system. This would potentially also reduce the proportion of cancers being diagnosed post-metastasis. Our argument is founded on the limitations of current screening practice, detailed as follows.

1. Initial Consultation with a Doctor

A patient meets with a general practitioner or breast specialist to discuss symptoms, family history, and risk factors. A physical breast examination is performed by a nurse or physician and a referral for further testing is provided if necessary. Patients with high-risk factors (family history, dense breasts) are typically referred for additional imaging.

2. Mammogram Screening

A mammogram involves X-ray imaging of the breast under compression. The breast is compressed between two plates, and detailed images of the breast tissue are

captured. The images are studied by radiologists to identify abnormalities. A standard mammogram typically takes 20 minutes, including preparation and imaging.

Mammography is the current screening standard globally for breast cancer.

There are two primary types of mammograms: traditional 2-dimensional mammography, which provides a flat image of the breast, and 3-dimensional mammography, which takes multiple images from different angles to create a more detailed, layered view. The latter provides improved sensitivity, reducing the chance of false positive diagnosis. Additionally, there is contrast-enhanced mammography (CEM), which involves injecting a contrast dye to highlight abnormalities. This is useful in evaluating suspicious lesions and in cases where Magnetic Resonance Imaging (MRI) (see next section) is not feasible.

Diagnosis via a mammogram requires radiologist interpretation of the X-ray image: there is a possibility for false positives and negatives.

While mammograms are effective in detecting breast cancer early, they have limitations. Firstly, the compression of the plates is highly uncomfortable and painful. This downside deters individuals from being screened. Mammography also involves radiation exposure, and, due to identification of abnormalities requiring interpretation of the image by a radiologist, there is the possibility of human error. More specifically, there is the possibility of false negatives – where an abnormality is not identified and tested further – and false positives – where an abnormality is identified erroneously and there is in fact no abnormality. Mammograms are also not suitable for women with dense breast tissue.

Dense breast tissue refers to breasts that have a higher proportion of glandular and fibrous connective tissue compared to fatty tissue. 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. This similarity can obscure tumours, reducing the sensitivity of mammograms and increasing the likelihood of missed cancer detections.

Mammography is not suitable for women with dense breasts (around 50% of the female Australian population) because dense breast tissue appears white, potentially masking cancers.

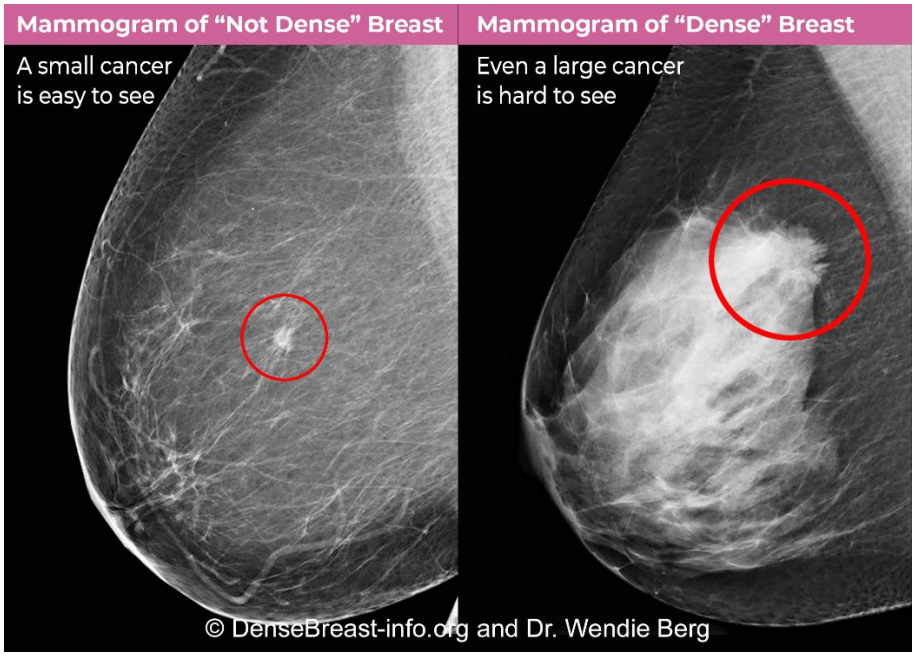

Figure 4: image courtesy of breastcancer.org highlighting the difficulty radiologists face in identifying cancers in patients with dense breasts.

In Australia, approximately 43% of women aged 40 to 74 have heterogeneously dense or extremely dense breasts, with the proportion decreasing with age: from 57% in

women aged 40 – 44 years to 26% in those aged 70 – 74 years. Studies indicate that breast density tends to be higher among Asian women. For instance, in Japan, high mammographic breast density was observed in 78% of non-symptomatic women and 87% of breast cancer patients. All in all, a significant proportion of women globally face a significant hurdle to breast cancer screening due to dense breasts. BREASTEST® bypasses this issue and is unaffected by breast density.

Looking at the types of mammography, neither 3D Mammography nor CEM are appropriate as a population-wide screening tool. 3D mammography, while improving cancer detection and reducing false positives compared to traditional 2D mammograms, takes longer to perform and interpret, increasing screening time and healthcare resource demands. It also involves slightly higher radiation exposure, which, although generally considered safe, could raise concerns if applied universally over multiple screening rounds in a large population. The use of intravenous contrast dye in CEM adds complexity to the procedure, increases costs, and carries a small risk of allergic reactions or kidney complications. Additionally, CEM is typically reserved for cases where standard mammography results are inconclusive or for high-risk patients needing enhanced imaging.

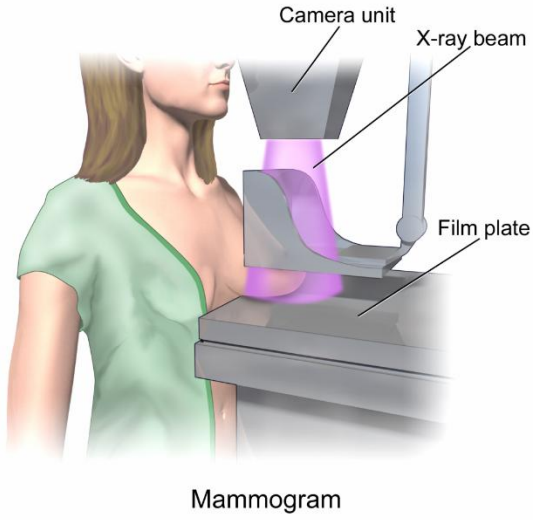

Figure 5: diagram showing how a mammogram is conducted.

3. Advanced Imaging: Ultrasound & MRI

If a mammogram is inconclusive, an ultrasound or MRI is recommended. Ultrasound imaging is a non-invasive technique that uses high-frequency sound waves to produce real-time images of breast tissue. It works by transmitting sound waves through a handheld transducer, which are then reflected to create detailed images of structures within the breast. The procedure typically takes about 15 to 30 minutes, depending on the area being examined and whether additional imaging is required. Breast ultrasound is particularly useful for evaluating abnormalities detected on a mammogram, distinguishing between solid tumours and fluid-filled cysts, and providing clearer imaging in women with dense breast tissue where mammography may be less effective.

MRI and Ultrasound are further diagnostic tools used typically in addition to a mammogram or in place of a mammogram in cases of dense breast tissue or cultural barriers.

One of its main advantages is the absence of radiation exposure, making it safe for repeated use, especially in younger women or pregnant patients. However, it has limitations, including a higher likelihood of false positives, leading to unnecessary

biopsies, and its dependency on operator skill, which can affect accuracy and consistency. Additionally, ultrasound alone is not considered sufficient as a primary screening tool for breast cancer because it may miss the small or early-stage tumours that mammography can detect. If ultrasound results are inconclusive or if further evaluation is needed, additional imaging such as MRI may be recommended, particularly for high-risk individuals or in cases where both mammography and ultrasound fail to provide definitive findings.

Magnetic resonance imaging (MRI) for breast cancer screening is an advanced imaging technique that uses strong magnetic fields and radio waves to create highly detailed, cross-sectional images of breast tissue. The procedure involves injecting a contrast agent, typically gadolinium-based, into a vein to enhance visualization of abnormalities, particularly in dense breast tissue or cases where mammography and ultrasound are inconclusive. A breast MRI typically takes between 30 to 60 minutes, during which the patient lies face down in a specialized coil while the scanner captures multiple images.

One of the primary advantages of MRI is its superior sensitivity in detecting small or hidden tumours, making it particularly useful for high-risk individuals, such as those with a strong family history of breast cancer or genetic mutations like BRCA1 or BRCA2. Additionally, MRI does not involve radiation exposure, making it a safer option for repeated screenings in certain populations. However, it also has limitations, including high costs, limited availability, longer scan times, and a higher rate of false positives, which can lead to unnecessary anxiety and additional procedures. Furthermore, some patients may experience discomfort due to the enclosed space or have contraindications such as implanted medical devices or kidney disease, which can restrict contrast administration. If an MRI is inconclusive or identifies a suspicious lesion, a biopsy is often indicated to determine whether the abnormality is malignant or benign.

4. Biopsy

A biopsy involves extracting a small sample of tissue for microscopic examination by a pathologist, who evaluates the cells for signs of cancer, ensuring that further intervention is only pursued when necessary. It is typically indicated when imaging tests such as mammography, ultrasound, or MRI reveal concerning findings that cannot be definitively classified.

A biopsy is a diagnostic tool used to confirm the presence of breast cancer. It is an invasive procedure typically performed once a mammogram and/or an MRI/Ultrasound are performed.

There are several types of breast biopsies, including fine-needle aspiration (FNA), core needle biopsy (CNB), and surgical biopsy, with CNB being the most used due to its balance of accuracy and minimal invasiveness. The procedure is usually performed under local anaesthesia and can take anywhere from 15 to 45 minutes, depending on the method used. Biopsies are highly accurate in diagnosing breast cancer, with core needle biopsy yielding a high degree of sensitivity and specificity, though in rare cases, sampling errors can occur if the needle does not extract representative tissue from the lesion.

The main advantage of a biopsy is that it provides a definitive diagnosis, allowing for appropriate treatment planning, but it also has drawbacks, including discomfort, a small risk of bleeding or infection, and, in some cases, the need for additional biopsies if results are inconclusive. Regardless of these drawbacks, the cost to the patient and

strenuousness of completing all steps up to and including a biopsy are significant. Avoiding mammogram, MRI, and biopsy where necessary would make the patient experience far more palatable, bolstering the case for BREASTEST®.

5. Diagnosis & Next Steps

Results from this series of tests are reviewed by a multidisciplinary team including radiologists, surgeons, and pathologists. If a cancer is confirmed, the patient is referred for treatment planning.

Discussion: Is There Demand for An Alternative Screening Process?

Surveys indicate women would prefer an alternative screening procedure to mammography.

Where BREASTEST® has significant disruptive value is ahead of step 2 – mammography. A survey conducted by Siemens Healthineers and HealthyWomen revealed that nearly 1-in-6 women reported that discomfort had deterred them from obtaining a screening mammogram as recommended. A systematic review published in The Breast journal in 2013 examined the impact of pain experienced during mammography on women's likelihood to participate in subsequent breast cancer screenings. The review analysed 20 studies and found that in the most robust studies asking women why they had not re-attended, 25% to 46% cited pain as a deterrent. The review also highlighted that women who previously experienced pain during mammography were more likely to fail to re-attend. These findings underscore the importance of an alternative screening tool.

A study conducted in Singapore explored women's preferences for breast cancer risk assessment tests, focusing on factors such as cost, methods to reduce late-stage diagnoses, and risk communication. The study of 28,104 individuals was conducted between 1994 and 1997 as part of the Singapore Breast Cancer Screening Project. It found that women prioritized the cost of the test and the potential to reduce late-stage breast cancer diagnoses. Notably, the method of risk assessment—whether through more frequent mammography, alternative screening methods, medication, or surgery—was a significant factor in their decision-making process. This suggests that women are open to various testing methods, including alternatives to traditional mammography, especially if these methods align with their personal preferences and offer potential benefits in early detection. While the study did not specifically compare blood tests to mammograms, the findings imply that if a reliable blood test for breast cancer screening were available, many women might prefer it over traditional mammography, particularly if it addresses concerns related to discomfort, cost, and accessibility.

Discussion: Overdiagnosis & Overtreatment

Overdiagnosis and overtreatment remains an issue and results in surgeries conducted on patients not in need of intervention.

Overdiagnosis and overtreatment of breast cancer are growing concerns in modern medicine, particularly with the widespread use of mammography screening. Overdiagnosis occurs when cancers that would not have caused symptoms or harm during a patient's lifetime are detected, leading to unnecessary treatments such as surgery, radiation, and hormone therapy. Studies estimate that 15% to 30% of breast cancers detected through screening may be over diagnosed, with rates increasing among older women. This results in overtreatment, exposing patients to physical, emotional, and financial burdens without improving health outcomes. The challenge lies in distinguishing between aggressive cancers that require intervention and slow-growing or indolent tumours that may never become life-threatening. To address this

issue, healthcare providers must adopt a more personalized approach to breast cancer screening and treatment, focusing on risk-based strategies and patient education to reduce unnecessary medical interventions while ensuring that high-risk cases receive appropriate care. This is another reason why BREASTEST® is a highly suitable complement to existing breast cancer screening methods.

Discussion: Is Mammography a Suitable Gold Standard?

Mammography is not particularly sensitive or specific, especially in cases of dense breast tissue.

According to the National Cancer Institute, the sensitivity of mammography ranges from 70% to 90%, depending on characteristics of the interpreting radiologist (level of experience) and characteristics of the patient (age, breast density, hormone status, and diet). Assuming an average sensitivity of 80%, mammograms will miss approximately 20% of the breast cancers that are present at the time of screening (false negatives).

Sensitivity decreases with increasing breast density. A 2019 study titled "Mammographic Density and Screening Sensitivity, Breast Cancer Incidence and Associated Risk Factors in Danish Breast Cancer Screening" found sensitivity was 78% in women with the least dense breasts (BI-RADS category 1) and dropped to 47% in those with the most dense breasts (BI-RADS category 4). Yale Medicine report that in extremely dense breasts, sensitivity can be as low as 30%. This reduction is due to the difficulty in distinguishing between dense tissue and potential tumors on mammograms.

Regardless of preference for breast cancer testing, we argue that an improvement over mammography is required to more reliably test for and diagnose breast cancer.

Precedent Tests: The Argument for BREASTEST® To Added to The Medicare Benefits Schedule

PSA Test

The Prostate-Specific Antigen (PSA) test is used to screen for prostate cancer, the most diagnosed cancer for men in Australia. It is provided by all major pathology practices in Australia. It measures the amount of PSA in the blood. High levels of PSA may indicate the presence of a cancer, requiring further examination. The Australian Institute of Health and Welfare estimates that 26,400 cases of prostate cancer were diagnosed in 2024, approximately 28% of the total number of cancers diagnosed in males for that year.

The PSA test is used to screen for prostate cancer. It is covered by Medicare in many circumstances.

The prostate cancer mortality rate has been steadily decreasing since the early 1990s: 62 deaths per 100,000 men in 1994, down to 33 deaths per 100,000 men in 2024. This has been aided by the PSA test's inclusion on Australia's Medicare Benefits Scheme (MBS) in 1989. The MBS recommends the test be done and provides a rebate for the test under five different itemised indications/situations ranging from:

- Item 66655 (low risk): standard testing for routine assessment for men with no previously diagnosed prostate disease and who are not at increase risk of prostate cancer due to family history. Medicare rebate is available every 23 months. In this scenario, the scheduled fee for the test is $20.15 and Medicare covers 85%.

- Item 66660 (high risk): for monitoring patients with previously diagnosed prostate-related conditions and who, put simply, remain at high risk based on previous PSA test results, family history, and age. Medicare rebate is available on up to 4 tests every 11 months. In this scenario, the scheduled fee for the test is $37.30 and Medicare covers 85%.

Since the introduction of the PSA test, prostate cancer survival rates have increased in Australia.

The 5-year survival rate of all prostate cancers in 2016-2020 was 96%. However, the survival rate drops to approximately 30-24% for cancers that have metastasized (i.e. those that have spread through the blood after not being detected early enough). In short, the PSA test's inclusion on the MBS scheme has facilitated earlier diagnosis of prostate cancer, leading to higher survival rates and better patient outcomes.

In Australia, approximately 21% of men aged 45-74, and 19% of men aged 75+ have a PSA test each year according to Medicare data. This equates to at least 1.17 million men receiving a PSA test each year. The total number of PSA tests is likely significantly higher given that many people receive more than 1 test per year.

The conventional first step in screening for prostate cancer is via a Digital Rectal Examination (DRE), an invasive and highly uncomfortable test involving a urologist physically feeling the prostate for abnormalities. This creates a barrier for many men to getting checked. The PSA test allows for more comfortable routine testing. While specific annual statistics on the number of DREs performed in Australia are not readily available, the prevailing clinical guidelines and practices suggest a preference among Australian men for the less invasive PSA test over the invasive DRE.

The PSA test sets a precedent for routine blood test monitoring for a specific cancer. Once BCAL attains regulatory approval from the Therapeutic Goods Administration (TGA) for BREASTEST® as an in-vitro diagnostic device, the company may submit an application to the Medical Services Advisory Committee (MSAC) for inclusion on the MBS.

ThinPrep Pap Test

ThinPrep is a liquid-based cytology (LBC) test that screens for cervical disease and sexually transmitted infections (STIs). It is used is Australia as part of the National Cervical Screening Program (NCSP) and is conducted at all major pathology service providers in Australia. It offers improved detection and sample quality compared to conventional Pap smears.

ThinPrep was developed to address the limitations of conventional Pap smears, such as uneven sample distribution and obscuring debris. It received FDA approval in 1996 and has since become a standard tool in cervical cancer screening programs globally, serving women of all ages.

A conventional Pap smear involves the following:

i. A healthcare provider collects cells from the cervix using a spatula, brush, or a similar tool.

ii. The collected cells are smeared directly onto a glass slide. This step often leads to uneven distribution of cells and the inclusion of debris which may obscure the view during microscopic examination.

iii. The slide is immediately fixed with a spray to preserve the cells and then is sent to a laboratory for analysis by a pathologist.

The ThinPrep Pap Test improves upon these limitations, offering a simpler, easier, quicker, and more cost-efficient alternative for patients:

i. Simpler sample preparation: the sample is rinsed into a liquid-filled vial rather than smeared on a slide, ensuring all collected cells are preserved for analysis. In the laboratory automated equipment creates a thin, even layer of cells on the slide, free from debris.

ii. Easier for patients: the ThinPrep method reduces the likelihood of unsatisfactory samples, sparing patients from the inconvenience of retesting. The same sample can also be used for HPV testing and other diagnostic tests, reducing the need for additional procedures.

iii. Quicker turnaround: lab automation expedites slide preparation and improves consistency, leading to faster results for patients.

iv. Cost efficiency: few unsatisfactory results mean lower overall healthcare costs for patients and providers. As ThinPrep has advanced diagnostic accuracy, it facilitates early detection of abnormalities and reduces the need for more extensive and expensive treatments down the line.

ThinPrep is a precedent for BREASTEST®, highlighting how a more accessible test increases testing prevalence and leads to better patient outcomes on a large scale.

The NCSP is one of Australia's three population-based cancer screening programs. Since its introduction in 1991, cervical cancer incidence and mortality has halved in Australia. Under current directives, a pap test is prescribed every five years for women aged 25-74. ThinPrep is covered under the MBS in specific circumstances. If oncogenic (tumour-causing) HPV is detected during the pap test, a reflex LBC, such as ThinPrep, is performed on the same specimen, and this combined testing process is subsidised by Medicare. However, if an LBC test like ThinPrep is requested without a prior positive HPV result, it is not covered by Medicare and will incur an out-of-pocket cost for the patient.

Evidently, the introduction of the NCSP in combination with the adoption of ThinPrep has greatly reduced the mortality rate of cervical cancer. This sets the precedent for more convenient and accurate diagnosis of breast cancer too.

Pathway to Addition On MBS

After obtaining NATA accreditation, BCAL must follow a structured regulatory pathway to have BREASTEST®, an in-house in vitro diagnostic (IVD) test, included in Australia's Medicare Benefits Schedule (MBS). Since in-house IVDs are developed and used within NATA-accredited laboratories rather than being commercially supplied, they follow a different regulatory framework compared to commercially available IVDs.

Step 1: Notifying the TGA

As an in-house IVD, BREASTEST®does not require full TGA approval but must comply with the TGA's in-house IVD framework. This requires BCAL to formally notify the TGA about the test. Laboratories using in-house IVDs must ensure their test meets the requirements of the Therapeutic Goods (Medical Devices) Regulations 2002. The notification process involves submitting information about the test's intended purpose, performance characteristics, and risk classification. Notifications are typically required by July 1 of the next financial year or within 20 working days of that date. Once notified, BCAL must continue to meet ongoing compliance requirements, including maintaining NATA accreditation.

Step 2: Preparing And Submitting an MSAC Application

To obtain MBS funding, BCAL must apply to the Medical Services Advisory Committee (MSAC) through the Health Products Portal. The first stage of this process is preparing a formal application that outlines the clinical utility, effectiveness, safety, and cost-effectiveness of BREASTEST®. This submission must provide robust clinical evidence and economic evaluations demonstrating the benefit of the test for public funding.

An initial pre-assessment process is conducted to ensure the application meets MSAC's requirements. The Population, Intervention, Comparator, and Outcomes (PICO) criteria must be defined and reviewed by the PICO Advisory Sub-Committee (PASC). This stage can take several months, as PASC meetings are scheduled periodically.

Step 3: Development of an Applicant-Developed Assessment Report

Once PASC approves the PICO framework, BCAL must prepare an in-depth Applicant-Developed Assessment Report (ADAR). This document provides a detailed analysis of the test's clinical effectiveness, diagnostic accuracy, economic evaluation (cost per test and cost-effectiveness in the healthcare system), and the overall impact on patient outcomes. The ADAR also includes real-world data where available, systematic reviews, and economic modelling comparing BREASTEST® to existing diagnostic methods.

If BCAL opts for a department-contracted evaluation rather than an ADAR, an external assessment entity will be assigned to conduct the evaluation, which can extend the timeline further. This phase is crucial as the strength and completeness of the evidence significantly influence MSAC's recommendation.

Step 4: MSAC Review and Assessment Process

After the ADAR is submitted, the MSAC review process begins. The Evaluation Sub-Committee (ESC) assesses the evidence and prepares a report for MSAC. The ESC meets quarterly, meaning that delays can occur if an application misses the next scheduled meeting.

Following the ESC review, MSAC conducts a final evaluation, considering the clinical, economic, and financial implications of adding BREASTEST® to the MBS. MSAC typically meets three to four times a year, and applicants may be asked to provide additional data or clarifications before a final recommendation is made. This step can take an additional 6–9 months, depending on the complexity of the assessment.

Step 5: Department of Health Decision & MBS Listing

After obtaining NATA accreditation, BREASTEST® must navigate a comprehensive regulatory process to be included in Australia's Medicare Benefits Schedule (MBS). The initial step involves submitting a completed application form to the Manager of the Pathology Section at Services Australia.

The process to be listed on the MBS may take between 18 and 24 months from initiation.

Following this, the application undergoes evaluation by the Medical Services Advisory Committee (MSAC), which assesses the clinical and cost-effectiveness of the test. The MSAC process can be extensive, often taking several months to over a year, depending on the complexity of the assessment and the completeness of the submitted data. Upon a favourable MSAC recommendation, the Department of Health and Aged Care considers the advice and, if approved, lists the test on the MBS.

It should be noted that the requirement for Therapeutic Goods Administration (TGA) approval prior to MSAC evaluation depends on the nature of the test. If BREASTEST® is classified as an in vitro diagnostic (IVD) medical device, it would typically require inclusion in the Australian Register of Therapeutic Goods (ARTG) before it can receive public funding. However, for new applications, the product is not required to have market authorization at the time of application form lodgement.

Competitive Landscape

Varied Approaches to Screening and Monitoring Breast Cancer Via Blood Testing

There is a broad range of technologies applied toward breast cancer blood testing, each with distinct advantages and limitations. BREASTEST® leverages lipidomics, a novel approach analysing lipid biomarkers that are uniquely altered in breast cancer patients. This method offers significant advantages, including high sensitivity and specificity, independence from breast tissue density, and cost-effectiveness. The key distinctions to be made when comparing tests are diagnostic vs prognostic, and early-stage detecting vs latter-stage detecting. As outlined previously, BREASTEST® is both diagnostic and capable of detecting early-stage cancer.

Circulating Tumour DNA (ctDNA)

One major area of competition stems from companies focusing on ctDNA analysis. These tests analyse fragments of DNA shed from tumour cells into the bloodstream. While promising for detecting advanced-stage cancers and providing insights into tumour characteristics, ctDNA-based tests for early-stage breast cancer face significant challenges.

ctDNA analysis looks at fragments of tumour cell DNA circulating in the blood.

ctDNA testing involves extracting DNA from a blood sample and analysing it using high-sensitivity techniques such as next-generation sequencing (NGS) or polymerase chain reaction (PCR). These methods identify tumour-specific alterations, including point mutations, insertions/deletions, and methylation patterns.

The pros of this technology include high precision in detecting specific mutations, and broad application – it is effective for detecting multiple cancer types simultaneously. However, early-stage tumours shed fewer cancer cells into the bloodstream than advanced-stage cancers. Consequently, ctDNA levels in the blood may be below the

detection limit of many current assays, resulting in poor sensitivity for detection of early-stage cancer.

Moreover, ctDNA testing is vastly more expensive than lipodmics-based testing: NGS is highly sophisticated and requires specialized laboratories and highly-trained personnel. Ultimately, this cost is passed on to the patient, making ctDNA far less accessible.

There are multiple companies developing a ctDNA-based breast cancer blood test. Grail's (NAS:GRAL) Galleri® test uses the technology to detect over fifty types of cancers. Galleri® analyses DNA fragments in the bloodstream for specific methylation patterns associated with cancer. The company claims that the test can also identify the likely tissue of origin for a positive result, meaning follow-up procedures may follow a more targeted path. Galleri's use case is testing of individuals who are at elevated risk for cancer, but it is not marketed as a replacement to routine screenings. While Galleri's accuracy varies by the cancer type being screened, it has shown very good specificity – 99.5% - but far lower sensitivity than BREASTEST® – 51.5%.

Galleri® is not sensitive for breast cancer. It is useful as a tool to screen high-risk patients for the possibility of cancer. It also does not compete with BREASTEST®on cost for the patient.

With CLIA certification, Grail has commercialised Galleri® and is actively selling the test in the US for US$949. It is available by prescription through healthcare providers. Grail has also signed partnership agreements: in February 2024, Curative Insurance Company included Galleri® as part of its member benefits, offering it with a zero cost. As of September 2024, Grail reported that over 250,000 Galleri® tests had been processed.

Grail spun-out of Illumina (NAS:ILMN) and started trading on Nasdaq on 25 June 2024. The company has a market capitalization of US$585m. For the nine months to 30 September 2024, the company reported $87.3m revenue for $1.93bn net loss. While sitting on US$853m cash at 30 September 2024, the company burned approximately US$484m in the nine months to this date. Grail presents as an investment with far greater risk than BCAL given this operational model: Grail must exponentially increase revenue to become profitable. This is unlikely until FDA approval (for which the company is yet to submit an application) and subsequently being covered by a CPT reimbursement code (which would reduce the cost to the consumer and promote adoption). When also considering Galleri's lack of sensitivity and broad (rather than specific and purposeful) use case, BREASTEST® provides a far more lucrative exposure to early-stage breast cancer diagnosis blood testing.

Cancerguard™ is a highly specific test but has far lower sensitivity than BREASTEST®for breast cancer. It cannot compete as a screening tool.

Another competitor in the ctDNA space is Exact Science and their Cancerguard™ blood test. Cancerguard™ is also designed to detect various cancers, including lung, colorectal, and liver cancers. It emphasises high detection rates for several common cancers. The company's ASCEND-2 study reported an overall sensitivity of 50.9% and specificity of 98.5% across 21 cancer types. Notably, when breast and prostate cancers were excluded, sensitivity increased to 56.8%. Like Galleri, the use case for Cancerguard™ is as an overall screening tool for high-risk individuals. And again, like Galleri, the test does not compare to BREASTEST® as a screening tool for breast cancer.

Other companies developing ctDNA blood test include Guardant Health, Natera, Foundation Medicine, Personalis, Labcorp, Volition, and Gene Solutions. Of these

companies, only Natera's Signatera test has been commercialised with breast cancer as a specific focus.

Signatera's use case (as it relates solely to breast cancer) is in the detection of ctDNA for molecular residual disease (MRD) assessment, treatment response monitoring, and early recurrence monitoring. Unlike BREASTEST®, it is not used as a screening tool. Clinical studies have demonstrated that Signatera can detect breast cancer recurrence with a sensitivity of approximately 88%, identifying relapse up to 38 months earlier than traditional imaging methods, with a median lead time of 10.5 months.

Signatera is covered by Medicare (US) for patients with stage II-IV breast cancer in the neoadjuvant setting (where treatment is given as a first step to shrink a tumour before the main treatment – typically surgery), regardless of subtype, and for stage IIb and higher breast cancer in the adjuvant and recurrence monitoring settings. In the Q3 2024, Natera performed approximately 137,100 tests. Natera operates under the CLIA certification with labs in Austin, Texas and San Carlos, California.

At this stage, the use cases of BREASTEST® and Signatera are distinctly different. We do not see Signatera being a screening-specific competitor to BREASTEST®.

Circulating Tumour Cells (CTCs)

CTC analysis involves identifying tumour cells shed into the bloodstream.

CTC analysis focuses on detecting tumour cells that shed into the bloodstream from primary or metastatic tumour sites. The detection and characterization of these cells are typically carried out using immunocytochemistry, flow cytometry, or single-cell RNA sequencing. These technologies enable the identification of specific surface markers or genetic aberrations unique to tumour cells, providing detailed insights into tumour biology.

This approach offers unique advantages, including real-time monitoring of tumour activity and treatment response. However, CTCs are more readily detected in metastatic cancers than early-stage cancers. Moreover, isolation and characterization methods require specialized equipment and expertise, raising barriers to widespread clinical implementation.

CELLSEARCH® is a blood test used to monitor already-diagnosed metastatic disease. It does not compete with BREASTEST® as it is not intended to screen for breast

Menarini Silicon Biosystems' CELLSEARCH® System is the first clinically validated and FDA-cleared blood test for enumerating CTCs, serving as a valuable prognostic tool in metastatic breast, prostate, and colorectal cancers. In metastatic breast cancer (MBC), studies have demonstrated that patients with elevated CTC counts (≥5 CTCs per 7.5 mL of blood) experience significantly poorer progression-free and overall survival compared to those with lower counts. For instance, a prospective multicentre study involving 92 MBC patients validated the analytical performance of the CELLSEARCH® System, confirming its reliability and high precision in detecting CTCs across repeated assays. Approximately 70% of these patients were found to have detectable CTCs, underscoring the system's robustness in capturing disease activity in advanced cancer stages. These findings highlight the utility of the CELLSEARCH® System in guiding treatment decisions and predicting disease progression in MBC patients.

However, as a prognostic tool, CELLSEARCH® is inherently limited to managing already-diagnosed metastatic cases, offering insights into disease trajectory rather

than aiding in the early detection of breast cancer. This distinction highlights the unique value of a diagnostic blood test like BCAL Diagnostics' BREASTEST®. While CELLSEARCH® provides valuable information for oncologists managing advanced cases, BREASTEST® is designed for non-invasive early detection, aiming to identify breast cancer at its earliest and most treatable stages. This functionality addresses a critical need in breast cancer care, as early detection significantly improves patient outcomes, particularly when treatment can be initiated before the disease progresses.

A diagnostic test like BREASTEST® also has broader utility in population-wide screening programs, potentially reducing the reliance on imaging technologies that may be limited by accessibility, cost, or patient-specific factors such as breast tissue density. Additionally, the ability of BREASTEST® to complement existing methods positions it as a transformative tool in enhancing early detection and improving survival rates for women globally. In contrast, while CELLSEARCH® serves an important role in metastatic cases, its application remains narrow, emphasizing the greater utility of diagnostic approaches like BREASTEST® in addressing the full spectrum of breast cancer management.

In addition to CELLSEARCH®, several other companies have developed CTC-based blood tests, each contributing to the growing landscape of liquid biopsy technologies. RareCyte offers an advanced platform that integrates blood collection with imaging and single-cell retrieval, enabling detailed characterization and molecular analysis of CTCs. This approach aims to provide insights into tumour biology while offering flexibility for research and clinical applications. CellMax Life specializes in early cancer detection, combining CTC and ctDNA technologies. Their tests are designed to identify cancer at its earliest stages, a critical factor for improving patient outcomes.

Epic Sciences has focused on isolating and analysing CTCs for both clinical decision-making and drug development. Their platform emphasizes single-cell analysis, helping to reveal tumour heterogeneity and resistance mechanisms. Meanwhile, Guardant Health, known primarily for its ctDNA assays, has incorporated CTC technologies into its broader liquid biopsy portfolio. These companies highlight the diversity of CTC-based approaches, from research and prognosis to early detection. However, while they provide valuable tools for understanding cancer progression and treatment response, they remain limited in their ability to serve as widespread diagnostic solutions, reinforcing the unique role of diagnostic assays like BCAL Diagnostics' BREASTEST® in the cancer care continuum.

Transcriptomics & Proteomics

Transcriptomics involves the comprehensive analysis of RNA transcripts produced by the genome, reflecting gene expression patterns under specific conditions. Proteomics, on the other hand, entails the large-scale study of proteins, which are the functional molecules driving biological processes and disease manifestations. Both approaches aim to identify biomarkers – molecules indicative of normal or pathological processes – that can facilitate early and accurate detection of breast cancer.

MASTOCHECK®, developed by the South Korean biotechnology firm Bertis, is recognized as the world's first proteomics-based blood test for the early diagnosis of

MASTOCHECK® is targeting the Asian market, thereby not having an initial overlap with Bcal's commercialisation strategy.

breast cancer. This innovative assay analyses three specific protein biomarkers which are associated with breast cancer presence. By employing mass spectrometry to quantify these biomarkers, MASTOCHECK® inputs the results into a proprietary algorithm to determine the likelihood of early-stage breast cancer. Clinical evaluations have demonstrated that MASTOCHECK® can detect early-stage breast cancer with an accuracy of approximately 92%, providing a convenient and non-invasive testing method that requires only a small blood sample. Notably, the diagnostic accuracy of MASTOCHECK® remains consistent regardless of breast density, addressing a common limitation of traditional imaging techniques.

In June 2022, MASTOCHECK® was confirmed as an after-entry medical technology by the National Evidence-based Healthcare Collaborating Agency (NECA) in South Korea, allowing its use in clinical practice for diagnostic purposes beyond health screenings. In September 2022, the company signed a contract with Raffles Medical Group to supply MASTOCHECK® to about 30 medical institutions in Singapore.

Both MASTOCHECK® and BREASTEST® are minimally invasive, utilizing simple blood samples to provide critical diagnostic insights. Therefore, MASTOCHECK® provides the greatest competitive risk to the successful commercialisation of BREASTEST®.

Valuation

We believe Bcal's long-term value will be derived from year-on-year growth adoption of BREASTEST®, initially in Australia, and then in US as well. While Asia also presents as a key market, to limit speculation and maintain conservatism in forecasting, we do not anticipate entry into this and other markets within the timeframe used for DCF analysis. We also do not assume addition to Australia's MBS during the forecasted period.

We place a fair valuation on BCAL Diagnostics of A$0.236 per share, approximately 114% upside from the current share price of A$0.11.

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
Implied (Target) Price	**$0.2363**

Figure 6: DCF summary table showing inputs to arrive at implied intrinsic value of BCAL (Target Price)

Our DCF model uses a WACC of 10.42%. The cost of debt uses a 15% pre-tax cost of debt and a 30% tax rate. The cost of equity uses a 4.1% risk free rate of return, a 12% equity risk premium, and a 0.8 beta. Calculating beta against the ASX Small Ordinaries index over 1 year of price data yields a figure of 0.5. Though, to be err on the side of conservatism, we incorporate the higher beta. We have estimated the company's free cash flows until FY30 and thereafter used a terminal growth rate of 6%.

Our forecasted FY30 revenue of A$26.10 (including both Australian and US operations) represents approximately 0.6% of the 2030 expected US-only breast

cancer screening market (US$2.34bn). Moreover, the forecasted number of tests performed in the US in FY30 – being 40,000 – is approximately 0.1% of the number of mammograms performed per annum in the US. We suggest that BCAL will continue to gain market share and adoption in this sizeable market.

Revenue Forecasting

Our revenue projections are based on a conservative view of Bcal's commercialisation efforts for BREASTEST®. We expect the company to conduct 1,200 tests in FY25 at an average price per test (net of discounts provided to certain patients) of A$290. To arrive at this quantum, we anticipate that around half of the estimated 30 patients presenting to Sydney Breast Clinic each day over 80 business days to the end of the financial year purchase a test. Over From FY26 and beyond, we expect this proportion to increase, facilitating approximately 4,500 tests done at SBC per annum in perpetuity. Moreover, we forecast that BCAL enters into commercial partnerships with other breast clinics and hospitals, facilitating the rollout of greater numbers of tests each year. With greater scale and to also promote greater market adoption, we anticipate BCAL lowering the price per test in a staged manner over the forecasted period.

We forecast that BCAL enters the US market in FY26 with a small initial rollout of approximately 1,500 tests but with quick adoption in the following years. We anticipate that in FY30, BCAL sells approximately 40,000 tests in the US at an average price of US$245. We have assumed that the exchange rate USD:AUD remains at 1.6 throughout the forecasted period. According to the FDA's Mammography Quality Standards Act (MQSA) National Statistics 42.8 million mammograms were performed in the US in 2024. Therefore, the assumption of 40,000 BREASTEST® tests are performed in FY30 represents a conversion rate of mammogram to BREASTEST® of less than 0.1% (i.e. 0.1% of US patients will opt for BREASTEST® in place of or alongside a mammogram). We believe this is a highly conservative prediction of US commercialisation success.

Expenses Forecasting

We anticipate that BCAL will continue to invest in R&D at a similar level to previous years. The company is actively engaged in research and development across multiple regions. In the United States, BCAL has established a subsidiary and secured laboratory facilities in North Carolina to drive its research and product development efforts. The company has also initiated collaborations with key physicians in Michigan and Chicago to accelerate its research initiative. In India, BCAL has partnered with the KIMS Institute and Indo American Hospital in Hyderabad to conduct feasibility studies, assessing the performance of their BREASTEST® technology in an Indian population.

Naturally, expenditure on consumables, personnel, and marketing will increase as commercialisation efforts advance, and consequently, as the number of tests sold and performed per annum increase. Though, as proven in recent years, we expect the company's leadership to effectively manage expenses and continue operating a lean capital expenditure model.

As detailed in the financial model (see Appendix II), we anticipate the company will invest in PPE to increase the operational capacity of the North Ryde laboratory in

Australia to accommodate at least 30,000 test per annum by FY30. The bulk of this expenditure we expect will be incurred in FY28.

Other Key Assumptions

We expect BCAL to pay off its equipment financing facility by the end of FY26. We do not anticipate the company will enter into another equipment financing facility upon investing in further PPE, rather using cash reserves to fund this expenditure.

As BCAL scales its operations, we anticipate accounts receivable as a percentage of revenues to decrease, suggesting refined operational performance with growth.

Sensitivity Analysis

		WACC						
	23.63	9.0%	9.5%	10.0%	10.4%	11.0%	11.5%	12.0%
Terminal Growth	4.5%	24.89	21.58	18.89	16.99	14.79	13.19	11.81
	5.0%	28.32	24.27	21.04	18.80	16.23	14.40	12.84
	5.5%	32.74	27.62	23.66	20.97	17.94	15.81	14.02
	6.0%	38.62	31.94	26.94	**23.63**	19.99	17.49	15.41
	6.5%	46.86	37.69	31.16	26.98	22.50	19.49	17.04
	7.0%	59.22	45.74	36.78	31.30	25.64	21.95	19.00
	7.5%	79.82	57.82	44.66	37.10	29.67	25.01	21.40

Figure 7: Sensitivity of target price to discount rate and terminal growth rate (base case scenario)

Additional Shares on Issue

Note that we have assumed a greater number of shares than are currently on issue. The company currently has ~365.97m fully paid-up shares outstanding. We anticipate the company will issue a further 120 million shares as part of capital raising initiatives as well as 4,501,596 from the exercise of existing options. We forecast no further options being issued in the forecasted period.

Key Risks

Competition risk: existing and/or new competitors developing and/or selling breast cancer screening blood tests may gain significant market share and inhibit the growth and success of Bcal's BREASTEST®. If another company successfully takes market share in jurisdictions inhabited by BCAL, BCAL not achieve forecasted revenues and may see an impact on margins. Moreover, there is the risk that an alternative screening tool (not a blood test) is developed, commercialised, and more widely adopted. This would hinder Bcal's growth and ability to continue as a going concern.

Regulatory risk: the approval process for in vitro diagnostic (IVD) tests varies significantly by country, and securing necessary certifications can be both time-consuming and costly. In Australia, BCAL has recently achieved a key milestone with the National Association of Testing Authorities (NATA) accreditation for its North Ryde laboratory, meeting ISO15189 and National Pathology Accreditation Advisory Council (NPAAC) standards. However, before full commercialization, the company must finalize analytical and clinical validation studies to obtain regulatory approvals necessary for listing BREASTEST® as an in-house IVD.

In the United States, BCAL plans to commercialize BREASTEST® as a Laboratory Developed Test (LDT), which traditionally falls under the purview of the Clinical Laboratory Improvement Amendments (CLIA) rather than the Food and Drug Administration (FDA). However, the regulatory landscape is evolving, and changes in

U.S. regulations could require FDA clearance, adding complexity and potential delays to market entry. BCAL has already initiated research and development operations in the U.S., including securing laboratory facilities in North Carolina and forming partnerships with key physicians and breast screening clinics in Michigan and Chicago.

The company also faces hurdles in other international markets. Applications for trademark protection and regulatory approvals are in progress in key jurisdictions, including the European Union, United Kingdom, China, India, Canada, South Korea, and New Zealand. Each region presents unique compliance requirements that must be met before BREASTEST® can be widely adopted. Moreover, regulatory delays in any one market could impact BCAL's ability to generate revenue and establish itself as a leader in breast cancer diagnostics.

Operational risk: despite securing key regulatory milestones such as NATA accreditation in Australia, BCAL must effectively navigate the transition from a research-focused entity to a commercially viable diagnostic provider. The phased commercial rollout, beginning with the Sydney Breast Clinic, is designed to refine the product's market fit. However, scaling beyond this initial site to a broader network of clinics requires substantial investment in sales, marketing, and clinician education. Additionally, market adoption depends on persuading healthcare providers, insurers, and patients of BREASTEST®'s advantages over existing mammography-based screening methods. If scepticism around clinical efficacy, pricing concerns, or reimbursement challenges limit uptake, BCAL may struggle to achieve sustainable revenues. Moreover, the test's reliance on laboratory infrastructure poses logistical hurdles – any delays in scaling operations, optimizing test processing efficiency, or securing distribution partnerships could hinder widespread adoption. A failure to gain traction in key markets such as Australia and the US may force BCAL to seek additional capital where potentially not expected to by the market, further straining financial resources and prolonging the path to profitability.

Intellectual property: As the pharmaceutical, biotechnology, and healthcare industries continue to evolve with rapid technological advancements, the protection of Intellectual Property (IP), including proprietary formulations, diagnostic technologies, and product designs, presents an ongoing challenge. BCAL's success somewhat depends on its ability to secure and maintain robust patent protection for its BREASTEST® technology and other innovations. The risk of IP disputes, patent challenges, or infringement claims from competitors or other industry players remains a key concern. Additionally, as new technologies emerge and regulatory landscapes evolve, there is potential for changes in patent laws, challenges to the validity of BCAL's patents, or difficulties in enforcing IP rights across different jurisdictions. Any adverse rulings in patent disputes or delays in securing IP protections could impact BCAL's ability to commercialize its products, defend its market position, or achieve long-term growth.

FOREX risk: Over the forecasted period, we suggest BCAL will operate in international markets, exposing the company to foreign exchange (FOREX) risk. Fluctuations in currency exchange rates may impact the company's financial performance, cost structures, and profitability, particularly as expenses related to research and development, regulatory approvals, and operational expansion are incurred in

different currencies. Changes in exchange rates could affect the valuation of international revenues, cost of imported materials, and overall operational expenses. Additionally, BCAL may face challenges in hedging against currency volatility, which could impact the predictability of cash flows and financial planning. A significant depreciation or appreciation of relevant currencies could lead to unexpected financial losses or increased costs, affecting the company's profit margins and competitive positioning in global markets.

Appendix

I. 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 Prospection.
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.
Mark Burrows AO 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.
Jonathan Trollip 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.
Dr John Hurrell 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.

II. Financial Forecasts

Income Statement							
A$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
Total Revenue	**3.10**	**3.43**	**4.76**	**6.87**	**10.36**	**16.99**	**26.10**
Operating expenses	-8.82	-8.78	-8.98	-9.63	-10.23	-10.53	-11.03
EBITDA	-5.72	-5.35	-4.22	-2.77	0.13	6.46	15.06
D&A	-0.58	-0.53	-0.60	-0.67	-0.96	-0.96	-0.96
EBIT	-6.30	-5.88	-4.82	-3.44	-0.83	5.50	14.11
Net Interest	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10
NPBT	-6.40	-5.98	-4.92	-3.54	-0.93	5.40	14.01
Tax expense	0.00	0.00	0.00	0.00	0.00	-1.62	-4.20
NPAT	-6.40	-5.98	-4.92	-3.54	-0.93	3.78	9.80
Weighted Avg Shares Out	246.23	347.98	406.66	432.18	432.70	434.43	436.17

Balance Sheet							
A$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
Current assets	9.34	9.75	9.56	6.42	4.33	9.23	19.90
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
Non-current assets	2.93	2.71	2.72	2.73	4.67	4.28	4.18
Total assets	12.27	12.46	12.28	9.15	9.01	13.51	24.08
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
Current liabilities	2.60	2.45	2.36	2.35	2.46	2.50	2.59
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
Non current liabilities	1.08	0.68	0.47	0.39	0.32	0.24	0.17
Total Liabilities	3.68	3.14	2.83	2.74	2.78	2.75	2.76
Net Assets	8.59	9.32	9.45	6.41	6.23	10.76	21.32
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
Total equity	8.59	9.32	9.45	6.41	6.23	10.76	21.32

Statement of Cashflows							
A$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
Operating cash flow	-4.52	-5.34	-4.46	-2.70	-0.44	2.99	8.29
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
Investing cash flow	-1.15	-0.50	-0.50	-0.50	-2.00	0.00	0.00
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
Financing cash flow	8.97	6.21	4.55	0.21	0.00	0.20	0.00
Cash flows	**3.30**	**0.37**	**-0.41**	**-2.99**	**-2.44**	**3.18**	**8.29**
Cash year end	6.47	6.84	6.43	3.44	0.99	4.18	12.47

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

Evolution Capital Pty Ltd
Level 8, 143 Macquarie Street Sydney, NSW 2000
Tel: +61283792960
www.eveq.com

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