



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Bcal Diagnostics

By **TIM BOREHAM**

**ASX Code:** BDX

**Share price:** 10.5 cents

**Shares on issue:** 252,294,714

**Market cap:** \$26.5 million

**CEO:** Shane Ryan

**Board:** Jayne Shaw (executive chair), Ron Phillips, John Hurrell, Jonathan Trollip, David Mark Burrows, Dr David Darling.

**Financials (half year to December 2023):** revenue nil, net loss \$2.4 million (previously \$2.47 million deficit), cash balance \$5.01 million (up 58%).

**Major identifiable shareholders:** Jayne Shaw 11.4%, Ronald Anthony and Ann-Marie Phillips 10.65%, Capital Property Corp (Carrington Account) 6.02%, Mera Vale #1 6.06%, Merchant Funds Management 4.4%

While most developers of health diagnosis tools scurry off to the capacious US market, Bcal is happy to use Australia as the springboard for what will be the country's first blood-based breast cancer assay.

"It's a passion of ours to launch the test in the Australian market and then take it global," says Bcal founder Jayne Shaw, a former nurse and entrepreneur who co-founded the Sydney Breast Clinic.

“We want this test available to all women, especially in the regional areas where it is easier to have a blood test than to access a mammogram.”

Here, 20,000 breast cancer cases are detected annually, with 3,000 deaths.

As a stepping stone to Therapeutic Goods Administration (TGA) approval, Bcal is developing its test, unoriginally monikered Breastest, as a so-called lab-developed assay.

Such tests can be sold via clinics once approved by the National Association of Testing Authorities (NATA).

“We are currently working in the US with regulatory bodies and focus groups, but the priority is a ‘soft’ market entry in Australia by the end of 2024,” Ms Shaw says.

She adds the company has had “open and frank” discussions with the TGA, which supports the lab-developed test approach.

## **The story of Bcal**

Bcal is an acronym of Breast Cancer Associated Lipids.

The company was founded by the Lancashire-born Ms Shaw, who migrated to Australia in 1990. She became the director of nursing and CEO of two NSW hospitals, where she noticed the poor results for breast cancer patients.

In 2000, she co-founded the eyecare clinic consolidation play Vision Group, which listed on the ASX and eventually was acquired by Chinese interests.

She then invested in the Sydney Breast Clinic, teaming-up with former New South Wales Liberal Party Health Minister Ron Phillips.

After the Sydney Breast Clinic was sold to Healthscope, the duo acquired the intellectual property pertaining to the blood-based tests.

Bcal listed on the ASX on July 19, 2021, having raised \$10 million at 25 cents apiece.

Some of Bcal’s intellectual property derives from Louisville University, which was replicating some of the scientific work.

In a management reshuffle announced on March 6 this year, current CEO Dr John Hurrell became a consultant and executive director.

The company’s chief operating officer since September 2023, Shane Ryan slipped into the CEO chair on April 1 ... no joke.

As a Genesiscare executive, Mr Ryan bought a genomics-based breast cancer test to market in 2021.

## **About Breastest**

The Breastest assay centres on lipids: fats that are a source of energy for cell growth.

“When the lipid metabolism is deregulated, this is the early sign of a cell becoming cancerous,” Ms Shaw says.

The blood sample is drawn from the patient and then the extracellular vesicles (EVs) are enriched from the blood plasma that contain lipids.

The blood is then matched against a panel of 18 biomarkers “characteristic of the presence of blood cancers”.

## **A facility you can (bio) bank on**

Flanked by polities including Federal Health Minister Mark Butler, last May Bcal opened its own lab in the Sydney suburb of North Ryde.

Rather than relying on potentially unreliable third-party biobanks, Bcal has 4,000 samples stored at the facility.

“We have collected 2,500 samples according to clinical protocols,” Ms Shaw says. “We haven’t just gone to bio-banks and that’s why it has taken us 14 years.”

Initially, Bcal will roll out the tests to New South Wales and Victorian centres including the Sydney Breast Clinic, Sydney’s Westmead and Royal Prince Alfred hospitals and Melbourne’s Monash Medical Centre.

Post launch, Bcal plans to seek agreements with local radiology providers to take the test nationally.

Costing around \$300 out-of-pocket, the algorithm-based test will be an adjunct to the commonly used mammography, which is a low-dose X-ray scan.

“You have to be realistic, you can’t replace the standard-of-care overnight,” Ms Shaw says.

## **Is Breastest the best test?**

Mammograms might be the standard-of-care, but they are far from optimal.

In Australia, 2.1 million mammograms took place in 2023, but a further 1.5 million eligible women did not get screened. Thus, 41 percent of women eligible for a mammogram choose not to do so, often because the procedure is uncomfortable or for cultural reasons.

Here, mammograms are not funded for under 40s women, unless they are deemed high risk because of a gene mutation.

The accuracy of mammograms leave much to be desired in terms of both sensitivity (the ability to detect tumors) and specificity (the ability to detect negative samples).

On these measures, mammograms are only 54.5 percent and 85.5 percent accurate respectively. Missed tumors aside, poor specificity means many follow-up biopsies are unnecessary.

With Breastest, Bcal claims a 90 percent sensitivity and 85.5 percent specificity.

Magnetic resonance imaging (MRI) scans are the most effective method, with an accuracy of 94.6 percent and 74.2 percent respectively. But they are expensive (\$900-\$1,200 a pop) and hard to access for all but the most vulnerable patients.

Dubbed the 'poor woman's MRI', contrast mammograms involve a contrast dye being injected to highlight the tumors better. This unreimbursed method is not widely available, takes 45 minutes and is dangerous to patients with allergies or compromised kidneys.

But Ms Shaw is heartened that while a lot of women don't want a mammogram, about half of those that undergo one will pay for extra testing out of pocket.

## **The road to the US**

Bcal is angling for US approval - initially as a laboratory test - which makes sense given the US accounts for 60 percent of the breast cancer diagnostics market.

More than 52.3 million mammograms were carried out in the US in 2019 and this year 310,720 cases of breast cancer were expected to be diagnosed.

Bcal has a tie up with the North Carolina-based diagnostics house Precion to validate the protocols and procedures for the clinical studies that will be needed to support regulatory approval.

Ms Shaw is pleased the results of the 656 US samples - drawn from stipulated ethnic groups - replicated the Australian accuracy.

Further down the track, Bcal is eyeing the market for post-treatment monitoring of women who have had breast cancer - a poorly-serviced cohort.

Bcal also has a licencing arrangement with the University of Louisville covering a similar blood assay for lung cancer.

"But I would rather get one thing right and then diversify, rather than being all things to all people," Ms Shaw says.

## **Finances and performance**

Despite a \$2.4 million half-year loss, Bcal's cash balance rose 58 percent to just over \$5 million at the end of December 2023, thanks to a placement and share purchase plan that raised just over \$3 million at 10 cents a share.

As of mid-March 2024 the company had \$3.6 million in the bank.

"The board is always evaluating capital requirements. There are no imminent plans but never say never," Ms Shaw says.

Other options are licencing agreements, or strategic partnerships.

Bcal shares have gained 35 percent over the last 12 months. Still, they are well below their peak of 25 cents of July 2021, just after listing.

## **Sizing up the rivals**

Blood-based diagnosis is a very active area globally, notwithstanding the reputational damage inflicted by US company Theranos and its jailed fraudster founder Elizabeth Holmes.

Ms Shaw is often asked questions about ASX-listed peer Rhythm Biosciences, which has developed a blood-based bowel testing assay to replace the unsavoury 'poo' test.

Rhythm has not cracked TGA approval and the test is being developed as a research-only tool. But another mob - Wisconsin's Exact Sciences Corp - has developed a US Food and Drug Administration-approved colorectal cancer test.

Bcal is also compared with the ASX listed Inoviq. The result of the merger of Bard1 and Sienna Diagnostics, Inoviq targets blood-based tests for breast and ovarian cancers, but its technology is based on antibodies rather than lipids.

Bcal's newest director, Dr Darling spent 17 years at the ASX-listed Pacific Edge, which took a bladder cancer test from New Zealand to the US but then struck reimbursement problems.

## **What's it worth?**

In the local market, Bcal has assumed Breastest penetration rates of 10 to 30 percent, with 20 percent equating to 400,000 tests and revenue of more than \$100 million.

Initially, Ms Shaw says, the company's laboratory should be able to do 20,000 tests a year across two mass spectrometer machines (which cost about \$500,000 each). This implies revenue of \$7 million.

Naturally, the company is seeking reimbursement and Ms Shaw notes other molecular-based tests for prostate, cervical and colorectal cancers are government funded.

Bcal has the ear of the pollies - including Federal Treasurer Jim Chalmers - which goes to show that breasts are always a vote winner.

“We realise there is not an unlimited budget, but can present persuasive data in view of reimbursement,” Ms Shaw says.

No pressure, Jim!

### **Dr Boreham’s diagnosis:**

Lest we forget, breast cancer is the world’s most common cancer for women, with two million new diagnoses a year and 627,000 deaths.

If diagnosed at stage one, the survival rate is 98 percent but this falls to 28 percent at stage four.

But let’s talk in real medical language: dollars. Bcal cites the cost of treating stage-one cancer cases at \$44,367, rising to \$418,549 by stage four.

The global testing market is worth about \$US5 billion (\$A7.5 billion) and is forecast to rise to \$US8.7 billion by 2027.

At the risk of stating the obvious, Bcal’s fortunes lie not so much with the broader and vast market potential, but in financial discipline and skilful execution of its plans.

On that note, Bcal’s board and management are replete with competent, commercial-focused operatives with the right intentions to boot.

Ms Shaw says the board treats every dollar as if it were its own, which is quite true as the directors account for a large wad of the register.

“We have never asked anyone to put a dollar in without backing it ourselves,” she says.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He doesn’t have an unlimited budget, but hopes he presents persuasive data.***