



24 March 2022

ASX Announcement

Shareholder Newsletter

BCAL Diagnostics Limited (ASX: BDX) (BCAL or Company) has pleasure in releasing a Shareholder Newsletter update.

This announcement has been authorised for release by the Board.

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Company Secretary

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About BCAL Diagnostics

BCAL Diagnostics Limited 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 91% specificity and 87% accuracy. The test is initially designed to complement current imaging technologies, such as the mammogram, with the aim of becoming a monitoring and screening tool suitable for women of all ages and backgrounds in any location. With more than two million new cases of breast cancer diagnosed globally each year, a substantial opportunity exists for BCAL to improve patient outcomes. BCAL has partnered with global integrated cancer care and cardiac provider GenesisCare to conduct clinical research required for regulatory approvals across several jurisdictions, commercialisation and market entry points.

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



Message from The Chair

I am pleased to be writing this latest update after a truly momentous period in the history of BCAL Diagnostics Limited ("BCAL" or "the Company"). Since mid-2021, we have made significant headway both in terms of our non-invasive breast cancer diagnostic technology and in the corporate aspects of our company.

On 21 July 2021, we achieved a pivotal milestone when we successfully listed on the ASX following an IPO that raised \$10 million from investors. This was the culmination of many months of hard work by the BCAL team. The proceeds of the capital raising have enabled us to fund important work on clinical development, intellectual property management, infrastructure development, quality management system establishment and implementation, algorithm development and validation and regulatory management.

In terms of our BCAL test, a recent independent analysis showed that, compared to previous analysis, a considerably reduced number of markers can be used to distinguish between blood samples of breast cancer patients and healthy people in our cohorts using the lipid-based test. This is an exciting development and improves our commercialisation prospects in the Australian, USA and European markets.

In late 2021, the results from a combination of Cohort 4 and Cohort 3 testing showed that our test had strong specificity and accuracy for an early-stage detection test based on an 18-lipid marker panel. This was consistent with previous results and reinforces the confidence we have in the potential of our test.

Around the same time, BCAL launched clinical studies in Sydney and Melbourne, with blood samples to be collected from 1,000 subjects. These studies will help to further validate our biomarkers, and to progress the test towards commercialisation as a viable and accurate blood-based diagnostic for breast cancer that will meet its initial intended purpose as an adjunct test to the mammogram.

On the personnel front, we have strengthened both our management and scientific teams. In August 2021, we recruited two highly skilled scientists with experience in lipidomics, mass spectrometry and data analytics, Dr Cheka Kehelpannala and Dr Mark David, to help accelerate the development of our breast cancer test.

More recently, we welcomed Dr John Hurrell as our CEO. Dr Hurrell is an experienced and highly respected corporate executive who has over 35 years' experience working in our industry. He has a strong track record in starting, building, and improving the profitability, performance and value of life science and healthcare companies, demonstrated by his many years across international roles. The Board have every confidence that Dr Hurrell will be ideal for BCAL as we continue to drive development of our technology to provide early and accurate breast cancer diagnosis to improve outcomes for patients.

With a strong leader at our helm and skilled scientists as part of our team, we are excited about the progress we will make in the rest of 2022. Thank you to our valued shareholders for the confidence they have placed in us and our experienced team and we will continue to keep you updated of our progress via the ASX and our electronic channels.

With kind regards,



JAYNE SHAW
 BCAL Diagnostics Limited Executive Chair



CEO Welcome

I am proud to bring you the first edition of our shareholder newsletter since becoming BCAL's CEO on 14 February 2022.

I have followed the Company's progress over the past decade as it made exciting progress towards developing a non-invasive blood test for the detection of breast cancer. I was honoured to be appointed as CEO to oversee a pivotal time for BCAL as we aim to achieve Australian and ultimately US and European regulatory approval for our technology.

I would like to take this opportunity to introduce myself to our valued shareholders. My career in life sciences and diagnostics spans over 35 years, during which I have developed and successfully commercialised multiple products and services within the industry. My varied experience ranges from developing and managing start-up and early-stage companies to executive roles with roles within a NYSE-listed, Fortune 500 clinical laboratory company. Most recently, I was Chief Commercial Officer at JanaCare, a remote chronic disease patient management company with a focus on diabetes and kidney disease.

I believe passionately that our technology has the potential to improve outcomes for patients by making a difference to the early detection of breast cancer, a disease that saw more than 2 million diagnoses in 2020. I very much look forward to bringing my extensive skillset and experience to help BCAL achieve its long-term goals.

Thank you for the warm welcome to BCAL. I look forward to keeping you up to date on the development of our breast cancer test and work towards regulatory approval in Australia.

With warmest regards,

DR JOHN HURRELL
BCAL Diagnostics CEO

Positive Independent Analysis

In February 2022, independent analysis of BCAL data in relation to our blood-based test for early-stage breast cancer detection showed that, compared to previous analyses, a considerably reduced number of markers can be used to distinguish between blood samples of breast cancer patients and healthy women (control group) in our cohorts using the BCAL test.

The BCAL test is designed to detect changes in the profile of lipids (fats) found in the blood, which is associated with breast cancer. Since 2018, we had originally collected blood samples from one group of women diagnosed with the most common type of breast cancer, invasive ductal carcinoma (IDC) accounting for 70% of invasive breast cancer cases and compared this with healthy women. This analysis indicated that 18 lipid markers could detect cancer in blood samples.

Subsequently, samples from a fourth cohort of patients that looks at three groups of breast cancer types were

examined compared to control samples, indicating that a reduced number of lipid markers, as few as 6 to 10, might be sufficient for an effective clinical test.

BCAL arranged for a third party to review the data and perform a retrospective analysis for the entire 790 samples collected. The review identified 5 lipid signatures encompassing a total of 12 lipid biomarkers, with 2 particularly strong markers identified more than once, was able to potentially detect cancer in blood samples with a high degree of reliability and consistency. BCAL's local blind testing findings are consistent with the third-party findings.

The results of the independent review reaffirmed our confidence in the BCAL test and paves the way for our commercialisation pathway in the Australian, USA and European markets.

Strong Cohort 4 Testing Data

In November 2021, we completed the processing of 301 samples as part of our Cohort 4 testing of the BCAL early-stage breast cancer detection test, with the positive results having the potential to accelerate development of the test.

The results produced from a combination of Cohort 4 and Cohort 3 testing are consistent with previous information provided on the specificity and accuracy of the early-stage detection test based on an 18-candidate lipid marker panel.

Reproducing these results to such a high standard reinforces the confidence we have in the potential of our

test and the ability of the BCAL team to develop innovative and credible diagnostic solutions.

We are looking to refine our algorithm and biomarker development. To this end, there is ongoing data analysis being carried out and we have engaged an international consulting group, with a wealth of relevant international expertise in the development of in vitro diagnostic products, to assist with algorithm optimisation.

These promising results paves the way for work on Cohort 5 and recruiting patients for the Stage 1 clinical trial of the BCAL test.

Australian clinical studies launched

BCAL launched the Australian clinical studies for our blood-based test for detection of breast cancer in November 2021 with our clinical partner, the Sydney Breast Clinic, collecting blood samples from patients having mammograms at its Sydney CBD location. The commencement of these studies is a key milestone for our company and is an important step towards validating our biomarkers and to progressing the test towards commercialisation of a viable and accurate blood-based diagnostic for breast cancer.

Stage 1 of the clinical program involves blood samples from 1,000 participants, which will be used to finalise the candidate biomarkers that should be used in the test to distinguish between women with breast cancer and those who are healthy, optimise the algorithm and establish protocols suitable for transfer of the test to commercial pathology laboratories.

The clinical program will also inform the design of the subsequent pivotal clinical trial which will be the basis for regulatory approval and will determine the clinical performance of the diagnostic test such that it will meet its initial intended purpose as an adjunct test to the mammogram in aiding a more accurate diagnosis of breast cancer.



Team expanded with key scientific hires

Since becoming a publicly listed company, BCAL has not only appointed experienced life science and healthcare executive Dr John Hurrell as our CEO, we have also bolstered our team with skilled scientists to accelerate the development of our breast cancer test. In August 2021, we recruited two highly skilled experts with experience in lipidomics, mass spectrometry and data analytics.

Dr Cheka Kehelpannala has over 7 years' experience in lipidomics and analytical chemistry in Australia

and Internationally. Dr Mark David has over 17 years' experience in analytical chemistry, metabolomics/lipidomics and mass spectrometry. Dr David joined us from the Imperial College London, which is a world leader in research, diagnosis, and treatment of diseases.

We are proud to have scientists of Dr Kehelpannala and Dr David's calibre join our team as we work towards regulatory approval of this groundbreaking non-invasive early breast cancer diagnosis test.

ASX listing & associated capital raising

On 21 July 2021, BCAL achieved a significant milestone in our history when we listed on the Australian Securities Exchange (ASX) following an Initial Public Offering (IPO) that raised \$10 million from investors. As a part of the offer, we issued 40 million new shares at 25 cents per share, valuing BCAL at \$51.7 million.

Our successful capital raising and listing on the ASX is a testament to the potential shown by our test and the calibre of our highly capable management team and board of directors, supported by a group of consultants

with substantial experience in clinical testing and development and commercialisation of diagnostic tests and related products.

Since then, the proceeds from the IPO have been used for further clinical development, intellectual property management, algorithm development and validation, infrastructure development, quality management system development and implementation and working regulatory management.

Breast cancer awareness month event

During October 2021, as part of Breast Cancer Awareness Month, we held a Breast Cancer Awareness Education Session led by a range of highly credentialed leaders in the space.

This included BCAL's Executive Chair Jayne Shaw, radiologist Mary Rickard, breast cancer surgeon Associate Professor Cindy Mak and radiation oncologist specialising in breast cancer Clinical Associate Professor Gillian

Lamoury. The session was chaired by renowned breast oncology and oncoplastic surgeon Associate Professor Sanjay Warrier.

If you missed the session, please watch the replay at the following link:

<https://www.youtube.com/watch?v=LK6CG8sKSpA&t=3494s>



What's next for BCAL?

As previously advised, we are working with Analytical R&D, who are assisting the scientific team with the tech transfer, from the current research laboratory into a commercial laboratory.

We have been working with a clinical lab, over the last 6 months, and the completion of the commercial agreement is in progress, and confirmation of this will be announced in due course.

The tech transfer is important as it will allow us to transfer the science to the USA. On return to the USA our CEO John Hurrell will continue to explore laboratory partnerships with the objective of transferring the science to a US laboratory. Other developments include:

US market entry

BCAL is working with Precision for Medicine on its USA market entry and reimbursement strategy.

Premier

is a US company working with BCAL on its data management requirements for continued clinical studies in Australia and the US market, which will assist us with our regulatory documentation requirements.

Clinical samples

we are currently exploring options to make it easier for members of the community to provide us with clinical samples, throughout Australia.

BCAL infrastructure

at this time we are recruiting a number of key positions who can work between the Australian and US markets to assist with market entry, product development and reimbursement.

Genesis Care

we continue to work with Genesis Care in relation to sample collection and market entry.



So Brave

Australia's only young women's breast cancer charity. We have initiated a relationship with this group of women in relation to sample collection, education, and future involvement of the BCAL test and with BCAL Diagnostics.

<https://sobrave.org.au/>



Finance

BCAL has the funds to execute its upcoming scientific program. As we have always been transparent with our shareholders, knowing that we are focused on the long-term deliverable of our test, we thank those that continue to support us along the journey. Since listing, we have strengthened the Company's foundation,

demonstrated that our scientific data is strong through an independent blind review, and the management and Board are continuing to execute the business plan. We believe shareholders will be rewarded in time and a positive difference to society will be made through our efforts.

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