

7 FEBRUARY ANNOUNCEMENT – ADDITIONAL INFORMATION

Breast cancer screening and diagnostic company BCAL Diagnostics Limited (ASX:BDX, 'BCAL' or the 'Company') is pleased provide additional information to supplement the announcement dated 7 February 2022, following analysis of its scientific data carried out independently by its Australian team and by a highly regarded team of international diagnostic experts.

BCAL Diagnostics provided scientific data on Cohorts 1, 2, 3, and 4, to be independently reviewed and retrospectively analysed in a strategic collaboration with BSC-Medical ('BSC') from the United States, involving Dr Szilard Voros, and Dr Aruna Bansal. Both experts have a proven track record in developing IVDs.

BSC analysed the data in a blinded fashion, without any access to prior in-house results. In this formal analysis conducted pursuant to a pre-specified Statistical Analysis Plan, candidate signatures were developed for five discovery sets. Overall, twelve lipids selected, with two lipids selected multiple times: lipid 1 (three out of five signatures) and lipid 2 (four out of five signatures).

Each candidate signature contained one or both of these lipids, and each candidate signature was supported by Area Under the Curve (AUC) > 70% in at least one other dataset. Two specific signatures developed for cohort 4 and combined cohorts 2+3+4 showed strong performance in the validations sets. To clarify, the cohort 4 signature was well supported by cohorts 2 and 3 with impressive AUC of 78% and 85% respectively. The cohort 2+3+4 signature (training set) was well supported by the 2+3+4 validation set with AUC of 83%. Acknowledging that the patients overlapped, these two signatures were very similar in composition, had only three lipids each, and two of the lipids were consistent, with a third lipid for each signature from one (the same) class of lipids. The supportive lipids were highly correlated. The findings demonstrated strikingly internally consistent results across all datasets. An overall accuracy of 77% was achieved in independent validation.

The results are especially exciting because when testing a signature on a never seen before data set, a considerable drop in performance (15-20% based on empirical testing) from training to testing sets is frequently observed while the algorithm is being developed and fine-tuned, which was not the case here for cohort 4 and the combined cohort 2+3+4 results (refer above AUC values). This lends itself to the strength of the identified signatures.

These signatures delivered strikingly consistent performance and are in agreement with BCAL's local blind testing findings. BCAL shared in November that the performance of cohort 3 and cohort 4 agreed using a panel of 18 lipids, resulting with an AUC of 85% and 84% respectively, and a cross-validated AUC of 89% in the combined cohort 3+4. BCAL has been working on locking its algorithm and identifying a reduced set of lipids that deliver reproducible performance.

Optimised testing of cohorts 2-3 showed an accuracy of 78% with only 6 markers, and average blind accuracy performance in cohort 4 using the same model equal to 76%. This indicates that BCAL independently arrived at similar findings to the external reviewers, and especially the potential to use a signature with a significantly reduced number of lipids between 6-10.

An in-house comparison of the 12 lipids identified by Dr Bansal to BCAL's results showed a 50% overlap despite the use of very different approaches. Furthermore, the 2 lipids in the most promising signatures identified by Bansal are part of BCAL's 18 lipid panel and 2 of the 12 are part of BCAL's locally optimised 6-lipid signature. This is a significant outcome given that the 12 lipids were identified out of 400+ candidates and half of them were mutually identified.

The combination of these local and international analyses supports BCAL's goal of reaching a refined algorithm, facilitating acceleration of test development in a format that will be attractive both clinically and commercially. In addition, this greater refinement of the lipid marker panel has opened the opportunity for BCAL to seek additional patent protection for its test.

The next stage is the consolidation of signatures to take through absolute quantification to be prospectively validated in a well-designed cohort after the completion of analytical performance validation.

In summary, the outcome of the analysis by the two teams is that a considerably reduced number of markers, compared with previous information, can be used to distinguish between blood samples of breast cancer patients and normal control samples. Such a reduction in the number of markers to be examined for each test considerably improves its commercial feasibility and attractiveness, reducing the time, cost and difficulty of analysis of each sample.

Dr Szilard Voros said: "We are very pleased with the results of our independent analysis at BSC Medical. We saw significant internal consistency in the data and were delighted to see that high areas under the curve (AUCs) could be achieved with a relatively small number of analytes. Our results make these lipid signatures rather conducive for commercialisation. We at BSC Medical are excited about future developments on this test, which will include moving to absolute quantification and deployment in carefully designed, prospective clinical studies to pave the way for commercialisation and launch, to bring this novel technology to women who need them the most."

Dr Aruna Bansal said: "The results were strikingly consistent across datasets: the same few lipids were identified in breast cancer patients across the spectrum of early-stage to late-stage disease. Initial estimates of prediction performance were highly promising and deserve urgent follow-up and joint development."

Bios

Dr Szilard Voros

Dr. Szilard Voros, MD, FACC, FSCCT, FAHA is a cardiologist, geneticist and serial entrepreneur. He is Founder and CEO of Global Genomics Group ("G3"), a precision-medicine-based biotechnology company, developing and commercializing novel drugs, nutraceuticals and blood-based biomarkers in common, chronic diseases, as well as for prevention, wellness and life extension.

Dr. Voros founded G3 in 2012. G3's platform is based on the largest-ever program using DNA and RNA sequencing, proteomics, metabolomics, lipidomics and other platforms. G3 has developed a diagnostic blood test for cardiovascular disease and has identified and is developing several novel drug targets. In 2020, G3 has announced a joint venture called Juvenomics in collaboration with one of the leading anti-aging biotechnology companies called Juvenescence. In addition, in 2020, G3 has also entered into an exclusive collaboration with Valo Health, a biotechnology company from within the Flagship Pioneering ecosystem.

Furthermore, Dr. Voros has founded VirTIGO Biotechnology as a spin-off from G3 in 2020, as a response to the COVID-19 pandemic. Dr. Voros recently also founded B4X, Inc., a new biotechnology company pursuing breakthrough treatments for the diseases of the brain. B4X, Inc. has been recently accepted into the Illumina Accelerator in San Francisco, CA for the March 2022 cycle. Dr. Voros is also founder of PUER Life, a wellness and longevity healthcare company anchored in biological Big Data.

Before G3, Voros was Chief Scientific Officer, Chief of Cardiovascular Prevention and Medical Director of Cardiovascular Imaging at Piedmont Heart Institute, where he utilized a combination of non-invasive imaging, blood-based biomarkers and genomics for cardiovascular prevention and life extension. Voros was also a critical participant in the discovery, validation, development and commercialization of a blood-based gene expression test for cardiovascular disease called “CorusCAD™”, which was featured as #7 on Time Magazine’s “Top Ten of Everything” in 2010. Voros was inaugural Chairman of the Scientific Advisory Board for HemoShear Therapeutics, LLC, starting in 2010. In addition, Voros was involved with the scientific design of the clinical program for Keystone Heart, a company that was subsequently sold to Venus MedTech, resulting in a listing on HKEX.

Voros has published extensively in major scientific journals including Nature Reviews, New England Journal of Medicine, Annals of Internal Medicine, Journal of the American College of Cardiology and Circulation: Cardiovascular Genetics, etc.

Dr Aruna Bansal

Aruna Bansal MSc PhD is Head of Digital Health at BSC-Medical and is an internationally renowned expert in multi-omics, biomarker data and biological big data, including real world data. With over 25 years’ experience in healthcare and forensics, she has made her mark as a leader in the pharmaceutical industry, in biotech IVD development, and in academic consortia. Dr. Bansal has been instrumental in the discovery, validation, and IP strategy in connection with several diagnostic biomarker signatures, including a mass spectrometry metabolomics-based diagnostic blood test for coronary artery disease developed by Global Genomics Group (G3). She has co-authored over sixty peer-reviewed scientific publications.

This ASX announcement has been approved for release by the Board of BCAL.

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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/>