ASX Announcement
30 January 2024

APPENDIX 4C – December 2023 QUARTERLY ACTIVITIES

- **Pre-analytical studies have been successfully completed and processing and storage parameters have been finalised**
- **Launch of the SENSIBLE study to assess final protocols and parameters determined as a result of the pre-analytical studies**
- **Commercial launch of BREASTEST™ remains on track for late 2024 with strong progress made in preparation for NATA Accreditation audit; positive feedback from informal advisory visit**
- **A second provisional patent application covering test details has been filed and the first application is undergoing accelerated examination**
- **Established a national network of Key Opinion Leaders with domestic and global influence to help facilitate the introduction of the test to the Australian market**
- **$5 million cash at bank as at 31 December 2023**

Breast cancer screening and diagnostic company BCAL Diagnostics Limited (ASX:BDX, 'BCAL' or the 'Company') is pleased to present its quarterly activities report for the quarter ended 31 December 2023.

BCAL is developing a blood-based test for detection of early-stage breast cancer. The test, BREASTEST™, is based on disease-associated changes in the profile of lipids (fats) found in blood. BCAL's BREASTEST™ (BCAL Dx) has consistently shown high sensitivity and specificity in detecting the occurrence of breast cancer and will supplement mammography, the current primary method for breast cancer screening. Market intelligence in Australia currently shows less than 50% of women between 50 and 74 get a mammogram,[1] where sensitivity and specificity varies dramatically by radiologist, and which is less effective in detecting disease in the early stage.

Completion of Pre-analytical Blood Processing Optimisation studies

As BCAL progresses towards the commercial launch of BREASTEST™, which remains on track for late CY24, the Company has now completed all studies to determine the tolerable limits and instructions for collection, transportation, processing and storage of patients' samples prior to pathology testing. This is important to ensure the results obtained are accurate and consistent.

These studies have enabled BCAL to confirm the final version of the protocol to be used for the product to be marketed globally. Scientific data to support the individual steps within the preanalytical protocol are important to demonstrate repeatable test integrity and for filing with the regulatory authorities.

Scientific Progress

To continue building on the findings of the clinical studies announced in the previous quarter, BCAL has initiated a further internally-managed clinical study, the SENSIBLE study, using samples from Australian patients collected and processed under the final protocol described above.

This study will continue into Q3 FY24 but an early analysis of the data being collected indicates continued

[1] BreastScreen Australia monitoring report 2023

concordance with the data collected in the US study previously reported, and earlier, locally-acquired data.

The Company is focused on the continual advancement of its technology and, as previously reported, studies are underway to uncover, from amongst the 20 lipids that constitute the Company's proprietary and patented lipid signature, a smaller group that will provide the highest performance of the test with reduced time and costs required.

Commercial pathway

BCAL is committed and remains on track to deliver a marketed product before the end of 2024.

BCAL's strategy is for BREASTEST™ to be initially made available as an in-house test, also known as a Laboratory Developed Test, (LDT). In order to achieve this, the laboratory that conducts the test must obtain NATA accreditation under ISO15189 and NPAAC.[2] Once the test has completed validation and is made available to patients, the Company will ramp up its commercial expansion strategy and secure additional clinical sites to conduct further clinical studies and generate the data required to support inclusion of BREASTTEST™ in the Australian Register of Therapeutic Goods.

As a priority, BCAL has been implementing procedures, protocols and quality systems required to meet NATA accreditation standards and, pleasingly in December, the Company received an informal advisory visit from the NATA auditor assigned to our case. The visit gave BCAL valuable information about the accreditation process and was very positive. The Company also received advice and guidance from the auditor on key focus areas to prepare for the formal pre-market audit, which is expected in mid-CY24.

Building robust Intellectual Property

During the Quarter, BCAL filed its second provisional patent application for its proprietary breast cancer test and the methods used to determine the indicative lipid signature. Pleasingly, the first provisional patent application, which was submitted in May 2022, has now entered the PCT (full patent) phase. This follows the application and receipt of an accelerated examination, the results of which were very positive. The application is now progressing well pertaining to the 24 claims included.

Sample Collection and partnership with KIMS Institute and Indo American Hospital, India

The Company is pleased to share that it has received outstanding support from clinicians of breast cancer patients and the collection of samples from Australian patients has continued and accelerated into Q2.

Delivering additional progress with diverse sample collection, BCAL successfully established a relationship with the KIMS Institute and Indo American hospital in Hyderabad, India to conduct a feasibility study for the collection of 290 samples from Indian breast cancer patients. The collection of samples will commence in Q2FY24 and the results of the study will assist in the development on the Company's global expansion strategy.

Since her visit in November 2023, A/Professor Dr. Gillian Lamoury is continuing to work alongside clinicians locally on behalf of the Company.

The bank of samples is an important resource for BCAL that can be interrogated rapidly as the Company explores how it can expand the range of ways in which BREASTEST™ can be used to assist breast cancer clinicians and their patients.

To house BDX's growing biobank of samples and associated meta data, it has invested in a biorepository system with -80°C freezers located at its North Ryde laboratory. This biorepository system allows BCAL to track samples and data more efficiently, and provides a risk mitigation back-up for these valuable

[2] **NATA** (National Association of Testing Authorities) is the leading accreditation organisation in Australia. **ISO 15189** is the international standard that specifies the requirements for quality and competence of medical laboratories. **NPAAC** (National Pathology Accreditation Advisory Council) is responsible for developing and maintaining the accreditation standards for Australian pathology laboratories.

samples.

BCAL's research team also continues to process and store samples at the NSW Health statewide BioBank, and has the ability to store samples in the US through its ongoing relationship with Precion.

Advocacy and Partnerships

During Breast Cancer Awareness month in October, BCAL Diagnostics partnered closely with Sydney Breast Cancer Foundation and So Brave in their fundraising events.

In November, BCAL Diagnostics hosted a valuable panel discussion with A/Prof Sanjay Warrier, Dr Cindy Mak, Prof Mary Rickard, So Brave founder, Rachelle Panitz and BCAL Executive Chair, Jayne Shaw. The event was led by Breast Cancer survivor and advocate, Claire Fabb and was attended by key media and medical professionals.

Also in November, the Company took a significant step in establishing a National Key Opinion Leader network. This dedicated network comprises experts who are committed to collaborating with BCAL, focusing on understanding and addressing the intricate clinical and patient needs ahead of the anticipated commercial launch in November 2024.

In December, BCAL presented an important poster at the San Antonio Breast Cancer Conference. The poster, titled *"Development of an Artificial Intelligence-based Breast cancer detection model using Plasma Lipidomic Signature",* was presented by Professor Bruce Mann for BCAL alongside COO, Shane Ryan. The response to the poster was excellent.

Financial report

Options

The Company raised $316,000 during the quarter on exercise of options. All directors exercised their options.

Financial performance

Research and development costs for the quarter were ~$1.6 million in line with budget and consistent with the program to get BREASTEST™ to market in 2024. These costs included an upfront part payment of $150,000 for an Orbitrap Exploris mass spectrometer.

Administration costs for the quarter of $0.52 million included costs of $78,000 relating to the preparation of the Research and Development offset claim, which was received during the quarter, in the amount of $3.047 million.

The Company has $5 million in cash and cash equivalents as at 31 December 2023.

Fees paid to directors for the quarter, being salary, superannuation and consulting fees, amounted to $101,000.

This ASX Quarterly Activities Report has been approved for release by the Board of BCAL Diagnostics Limited.

A Shareholder webinar and update will be held in February 2024. More details on the webinar will be released to the market in due course.

ENDS

For further information:

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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 90% sensitivity and 85.5% specificity. 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.

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

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
BCAL Diagnostics Limited	
ABN	**Quarter ended ("current quarter")**
97 084 464 193	31 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(1,569)	(3,146)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs (non R&D)	(133)	(240)
	(f) administration and corporate costs	(518)	(998)
1.3	Dividends received (see note 3)		
1.4	Interest received	1	5
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material) R&D Tax Offset	3,047	3,047
1.9	**Net cash from / (used in) operating activities**	**828**	**(1,332)**

2.	**Cash flows from investing activities**	-	-
2.1	Payments to acquire or for:	-	-
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	240	3,005
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	316	368
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(198)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)		
3.10	**Net cash from / (used in) financing activities**	**556**	**3,175**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,633	3,174
4.2	Net cash from / (used in) operating activities (item 1.9 above)	828	(1,332)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	556	3,175
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**5,017**	**5,017**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	4,014	2,632
5.2	Call deposits	1,003	1,001
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**5,017**	**3,633**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	101
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Items in 6.1 related to payments made for Directors fees

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	828
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,017
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,017
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?
Answer: N/A	

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 30 January 2024.....

Authorised by: The Board.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.