

ASX Announcement

26 April 2024

APPENDIX 4C – MARCH 2024 QUARTERLY ACTIVITIES

- **First two stages of the SENSIBLE study refining the lipid panel for BREASTEST® successfully completed. Study provided initial data to reduce complexity, cost of the test and also improve robustness**
- **Appointment of CEO, Shane Ryan to lead commercial launch and growth of BREASTEST®**
- **Appointment of Non-Executive Directors, David Darling; and former CEO John Hurrell to become NED and Consultant**
- **Notice of intent to grant received for an additional European patent**
- **National network of Key Opinion Leaders established with domestic and global influence to help facilitate the introduction of BREASTEST® to the Australian market**
- **Sample collection to facilitate SENSIBLE study 3 accelerated with seven collection sites now operational across Sydney and Melbourne**
- **\$3.3 million cash at bank as at 31 March 2024**

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 March 2024.

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

Scientific progress

BCAL's internally managed SENSIBLE studies, announced in Q2 24, have now successfully completed. These studies used prospectively collected Australian samples that were not previously analysed, to provide refinement of the lipid panel for BREASTEST®. The early SENSIBLE data is consistent with those collected in previous studies.

SENSIBLE-1 and SENSIBLE-2 studies have enabled the reduction in the number of lipids required for an accurate and effective test (breast cancer signature), previously 20 lipids were required. This is an important step in the development of a commercial test since the reduction of the number of lipids in the panel reduces the complexity of the test, reduces the overall test costs and improves the robustness of the test.

The next stage, SENSIBLE-3, is scheduled for completion late next quarter (Q4 FY24) and will include a significantly larger number of patient samples. These samples are currently being prospectively collected from sites across Australia. This final internally managed study will be used to confirm the results from

¹ BreastScreen Australia monitoring report 2023

the first two SENSIBLE studies and finalise the lipid panel and diagnostic algorithm. This step is required prior to analytical method validation and final preparation for the clinical validation study.

Management transition and board appointment

As part of BCAL's commercialisation strategy, Shane Ryan was promoted to the position of Chief Executive Officer during the quarter. Shane has an excellent track record of success and brings a wealth of biotechnology product commercialisation experience from his previous role as Global SVP of Strategy & Innovation - Patient Access at GenesisCare. In 2021 Shane brought to market a test for breast cancer patients which was successfully launched in Australia and is now available nationwide. Shane's commercial product launch experience will be vital in ensuring a successful launch of BREASTEST® in late 2024. Shane's tenure as CEO commenced on 2 April 2024.

Dr John Hurrell joined BCAL's Board of Directors as a Non-Executive Director and consultant, after stepping down from the role of CEO. John will provide ongoing advice in relation to the scientific product development, laboratory scaling and commercial operations as well as preparing for a subsequent launch in the USA.

Mr David Darling was also appointed as Non-Executive Director during the quarter with effect 1 March. Mr Darling replaced Dr Marilyn Sleight who retired from the Board. Mr Darling has a background as a scientist with a specialty in genetics and has more than three decades of experience developing and commercialising life sciences and biotechnology products which will be an asset to BCAL as it reaches the final stages of commercialisation of BREASTEST®.

Building robust intellectual property

During the quarter BCAL worked with the US-based patent attorneys prosecuting the patent applications which the company has licensed from the University of Louisville. Excellent progress has been made in completing the patent office requirements for pending patent applications in Europe, the US and Canada. Pleasingly, a notice of intent to grant was received for an additional European patent during the quarter. This application, EP 21200018.6, was nominated to be entered in eight key European countries, bringing BCAL's total patents issued, or granted, to eight.

The Company received Australian notice of registration for the Trademarks BCAL Dx® and BREASTEST® in April. The Company has submitted trade mark applications for both BCAL Dx® and BREASTEST® in other major markets including the USA, UK, Europe, China and India.

Sample collection continues at an accelerated pace

The Company continues to work closely with clinicians who manage breast cancer patients. These relationships are crucial to the collection of patient samples for BCAL's development activities including the SENSIBLE study 3. Samples are collected and processed according to a strict protocol developed by BCAL to ensure the consistent quality of samples reaching the laboratory.

During the quarter BCAL brought several new collection sites on board and now are actively collecting patient samples from seven sites across Sydney and Melbourne. BCAL have eleven additional sites pending with ethics and governance approvals at different stages including four international sites with two in the US and two in India.

Advocacy and partnerships

BCAL's National Key Opinion Leader network has continued to provide clinical guidance and support to the company's development activities. The Key Opinion Leader group has grown again this quarter with the recruitment of two more of Australia's leading breast oncologists.

A meeting of the network was held in March to discuss BCAL's commercialisation plans and how BREASTEST® will be positioned in the current clinical pathway for patients. The leadership from this

group has been invaluable to BCAL as the Company moves into the final stages of commercialising BREASTEST®. Notably, the group has been instrumental in accelerating BCAL's sample collection, shaping the Company's market access program and providing ongoing research as well as bridging new partner opportunities.

BCAL has continued to form strong partnerships with breast cancer advocacy groups such as SoBrave, Sydney Breast Cancer Foundation and Pink Hope. These organisations represent women who are known to have a high breast cancer risk and their members are supporting BCAL's efforts in developing BREASTEST®.

During March BCAL's Executive Chair, Jayne Shaw, participated in several high profile panel discussions supporting International Women's Day.

Financial performance

Research and development costs for the quarter were ~\$1.4 million in line with budget and consistent with the program to get BREASTEST® to market in 2024.

Administration costs for the quarter were \$0.17 million

The Company has \$3.3 million in cash and cash equivalents as at 31 March 2024.

Fees paid to directors for the quarter, being salary, superannuation and consulting fees, amounted to \$97,000.

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

ENDS

For further information:

Jayne Shaw

Executive Chair
Jshaw@bcaldiagnostics.com

Shane Ryan

Chief Executive Officer
sryan@bcaldiagnostics

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 excellent performance independent of breast tissue density. 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/>

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Appendix 4C

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

Name of entity

BCAL Diagnostics Limited

ABN

97 084 464 193

Quarter ended ("current quarter")

31 March 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,377)	(4,523)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs (non R&D)	(112)	(352)
(f) administration and corporate costs	(174)	(1,172)
1.3 Dividends received (see note 3)		
1.4 Interest received	1	6
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
1.9 Net cash from / (used in) operating activities	(1,662)	(2,994)
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 (9 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)	-	3,005
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	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	-	3,175

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,017	3,174
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,662)	(2,994)

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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)	-	3,175
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,355	3,355

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	84	4,014
5.2	Call deposits	3,271	1,003
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)	3,355	5,017

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	97
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
<i>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.</i>		
Items in 6.1 related to payments made for Directors fees		

7. Financing facilities <i>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.</i>	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)	(1,662)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,355
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	3,355
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.02
<i>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.</i>	
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: 26 April 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.