

ASX Announcement

30 July 2024

## APPENDIX 4C – June 2024 QUARTERLY ACTIVITIES

- **Successful placement raising \$10.5M, with funds to be used to accelerate path to commercialisation**
- **SENSIBLE 3 study tracking to complete on-time**
- **BREASTEST Clinical validation study opens recruitment**
- **Trade mark BCAL Dx<sup>®</sup> now registered in the United Kingdom**
- **\$6.5 million cash at bank as at 30 June 2024**
- **Capital Raise successfully completed with \$10 million cash at bank mid July 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 30 June 2024.

**Executive Chair, Jayne Shaw commented:** "This quarter marked an inflexion point for BCAL on its path to commercialising its breast cancer blood test, raising \$10.5 million via an oversubscribed placement supported by a range of institutional and sophisticated investors as well as our Directors and Management. Through this process BCAL reached an important milestone, with more than 1,000 shareholders. The BCAL team were delighted with the progress of the company and the positive market response to the capital raise. This is strong recognition of BCAL's progress towards commercialisation and the maturity of the program."

The Company continues to rapidly advance its clinical entry strategy, collaborating with industry leaders, and advancing discussions with potential partners to bring the breast cancer blood test to market, and fulfill the Company's mission of improving diagnostic outcomes for cancer.

### **Product Development and Scientific progress**

Recruitment to the Company's SENSIBLE-3 study is nearing completion. The 600 samples have been prospectively collected from a number of sites across Australia. The analysis of this study will enable BCAL to finalise the selection of the lipids used in the commercial version of BCAL's breast cancer test. An abstract of the pending SENSIBLE-3 study results has been accepted as an oral presentation at the **8th World Congress on Controversies in Breast Cancer conference (CoBrCa) 2024**, to be held later this year in Edinburgh, Scotland.

During the quarter BCAL opened recruitment of its clinical validation study, The BREASTEST study. This is a significant clinical study required to support uptake of BREASTEST<sup>®</sup> by clinicians and necessary for the regulatory pathway. The BREASTEST<sup>®</sup> study design requires a minimum of 460 patients recruited from at least seven breast screening clinics across three Australian states and territories.

The BCAL team has made a major advance in reducing the BREASTEST<sup>®</sup> commercial patient sample processing time in the laboratory in North Ryde, resulting in a pleasing increase in production capacity. Testing capacity will be approximately 50% greater than previously estimated making the test available to more women on an annual basis without any further capital investment in the Clinical Laboratory.

### **Clinical laboratory and accreditation**

During the quarter BCAL made a significant capital investment in its state-of-the-art clinical laboratory and patient sample processing facility, including a sophisticated liquid handling robot, that will assist with automation and the installation of three commercial grade mass spectrometers. This investment lifts the commercial capacity to more than 100,000 tests per annum.

BCAL continued to make substantial progress in relation to accreditation of the laboratory. Quality systems and documentation required for assessment of the laboratory by NATA is nearing completion and we look forward to our assessment visit in the next quarter.

### **Building robust intellectual property**

#### *Patents*

During the quarter, BCAL continued to prosecute patent filings in its growing portfolio, with three national phase applications and one PCT phase filing pending.

#### *Trademarks*

BCAL is seeking trademark protection for the name of its first product, BREASTEST®. This mark has already been registered in Australia, with registration pending in jurisdictions where the product is likely to be sold, including:

- USA
- EU
- UK
- Canada
- China
- India
- South Korea
- New Zealand

During the quarter, the BCAL Dx mark was registered in the UK.

### **Advocacy and partnerships**

#### *Australia*

BCAL's National Key Opinion Leader network has continued to provide clinical guidance and support to the company's clinical study and market entry activities. We continue to work with breast cancer surgeons and multidisciplinary teams.

#### *United States of America*

Dr Eric Brown, a leading breast surgeon from Michigan Healthcare Professionals is the Principal Investigator (PI) for recruitment of patients to BCAL's initial clinical study in the USA. The first patients to this study were recruited in June, which is a major step forward to establishing the necessary evidence BCAL will require for the eventual market entry in the USA.

**Dr Brown said** "I am thrilled to be collaborating with BCAL Diagnostics on this exciting study. I believe that the BCAL science is very solid, and BCAL has demonstrated that they really understand the needs of physicians and patients. Working together we hope to be able to significantly improve the outcomes for women with Breast Cancer in the USA."

## **Financial report**

### **Placement**

BCAL raised \$10.5 million, before costs, through a placement for the issue of 105 million new fully paid ordinary shares at an offer price of \$0.10 per new share.

The funds raised are being used for the market launch of BCAL's blood test in Q4 of CY 2024 as well as preparation for market launch into the US in 2025. Funds will be used for further product development and research including costs associated with clinical trials and regulatory. The raise will enable facilitation of commercial production via expanding BCAL's clinical services laboratory with equipment and staff following NATA certification of ISO15189 as well as bolstering general working capital.

New shares under the placement have been issued under two tranches:

#### **Tranche 1 (pre 30 June 2024)**

- a) 37,000,000 shares within the Company's existing placement capacity in accordance with ASX Listing Rule 7.1.
- b) 25,000,000 shares within the Company's existing placement capacity in accordance with ASX Listing Rule 7.1A.

#### **Tranche 2 and directors shares (post 30 June 2024)**

43,000,000 shares have now been issued following shareholder approval at a General Meeting held on 15 July 2024.

### **Financial performance**

Research and development costs for the quarter were ~\$2.1 million in line with budget and consistent with the program to get BREASTEST® to market in CY2024.

Administration and non R&D staff costs for the quarter were \$0.4 million.

The Company has \$6.5 million in cash and cash equivalents as at 30 June 2024, and a further \$3.9 million relating to the capital raise was received in July 2024.

Fees paid to directors for the quarter, being salary, superannuation and consulting fees, amounted to \$154,000.

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 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")**

30 June 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(2,055)	(6,578)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs (non R&D)	(152)	(503)
(f) administration and corporate costs	(268)	(1,442)
1.3 Dividends received (see note 3)		
1.4 Interest received	41	48
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
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,434)</b>	<b>(5,428)</b>
<b>2. Cash flows from investing activities</b>	<b>-</b>	<b>-</b>
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 (12 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	(694)	(694)
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(694)</b>	<b>(694)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	6,200	9,205
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	369
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(234)	(432)
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 – advance on capital raise	280	280
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>6,246</b>	<b>9,422</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	3,355	3,174
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,434)	(5,429)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(694)	(694)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,246	9,422
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,473</b>	<b>6,473</b>

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	84
5.2	Call deposits	3,271	3,271
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>3,355</b>	<b>3,355</b>

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	154
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. <b>Financing facilities</b> <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>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,434)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,473
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,473
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	2.7
<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: 30 July 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.