

**ASX Announcement**

31 October 2024

**APPENDIX 4C – September 2024 QUARTERLY ACTIVITIES**

- **Commercial license agreement with Sydney Breast Clinic (SBC)**
  - **SBC selected as initial clinical development and commercialisation partner for BCAL's breast cancer detection tool**
  - **Agreement to enable patients of SBC being able to access BCAL's BREASTEST®**
- **Commenced US research operations, with establishment of US subsidiary and lease of laboratory facilities secured**
- **NATA laboratory audit completed on 30 September and assessment in progress. An outcome recommendation from NATA should be available in the coming weeks.**
- **SENSIBLE 3 study analysis has been delayed but is nearly complete. We are preparing for the clinical validation study, which is on track**
- **\$7.1 million cash at bank as at 30 September 2024, with further ~\$2.6 million to be received from R&D tax offset**

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 September 2024.

**CEO, Shane Ryan commented:** "BCAL has been focused on readying itself for the commercial launch of BREASTEST®. This quarter we were pleased to secure a commercial license agreement with the Sydney Breast Clinic (SBC), confirming that it will be the first site in Australia to offer BREASTEST®. SBC has been an invaluable clinical partner for BCAL over the past 6 years and we are delighted to be working with them as we launch BREASTEST®."

*We have worked hard to prepare our laboratory for its NATA assessment, recently completed and pending their report. We will be thrilled to have this accreditation, an essential element to reaching our commercialisation goals.*

*Our operations in the US commenced during the quarter which will complement the science team in Australia and accelerate our entry into this market."*

**Product Development and Scientific progress**

Product development and scientific operations continued throughout the quarter and are crucial to ensuring BREASTEST®'s readiness for the Australian market entry. This includes testing for repeatability and sample integrity, from sample collection through to producing a result for the patient. Among the key studies completed this year is the verification of our lipid signature test within an Australian cohort, known as the SENSIBLE studies. We eagerly await the analysis of sensible 3 which is nearing completion.

Our clinical validation study, the BREASTEST STUDY is recruiting ahead of schedule. This study will confirm the performance of our test in the target population.

**Clinical laboratory and accreditation**

BCAL continued to make substantial progress in relation to the accreditation of its laboratory. Quality systems and documentation required for assessment of the laboratory by NATA (National Association of Testing Authorities) is now complete. NATA are currently finalising the assessment of BCAL's laboratory and the Company expects to hear the outcome in the coming weeks.

### ***Commercial license agreement***

In September we signed a commercial license agreement with one of the leading multidisciplinary private breast clinics in Australia, the Sydney Breast Clinic. This will be our first center for clinical development, and secure our first site in Australia to offer BREASTEST®. Sydney Breast Clinic has been an invaluable clinical partner for BCAL over the past 6 years, recruiting women to donate samples to help BCAL develop and validate BREASTEST®.

### ***Commencement of US operations***

During the quarter, BCAL established a North Carolina, United States of America, incorporated wholly owned subsidiary, BCAL Diagnostics, Inc which commenced operations on 2 September. This has enabled BCAL to secure laboratory facilities in the region, underpinning the company's plan for research and development in the U.S.

We were excited to announce that we have appointed a full-time Director for our U.S. Research and Product Development program – Dr Klaus-Peter Adam, a distinguished scientist specializing in metabolomics and lipidomics, further enhancing our global research expertise. Joining Dr Adam is Dr Haibo Wan, together making an incredible Research and Product Discovery team, and Ms Cory Dunn (Consultant), who has a wealth of marketing experience and knowledge of US breast cancer networks.

Expanding into the US means that we are working on solutions developed by global thought leaders around the clock, accelerating BCAL's knowledge and development at an unprecedented rate. In addition, BCAL has been driving collaboration programs with key physicians in targeted sites with the first two sites, Michigan and Chicago completed and more sites in process.

### ***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. During the quarter it was registered in the European Union and the United Kingdom with registration pending in jurisdictions where the product is likely to be sold, including:

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

Registration for BCAL Dx® was granted in China, the European Union and New Zealand during the quarter, with the trade mark also registered in Australia and United Kingdom earlier this year. Registration is pending in further jurisdictions:

- USA
- Canada
- India
- South Korea

### ***Advocacy and partnerships***

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 are working closely with breast cancer surgeons and multidisciplinary teams.

### ***Financial report***

#### ***Share Placement***

The Share Placement to raise \$10.5 million announced in June 2024, was completed in July 2024 following shareholder approval of additional capacity.

In total the Company issued 105 million shares at \$0.10 per share.

#### ***Financial performance***

Research and development costs for the quarter were \$1.4 million.

Administration and commercialisation costs for the quarter were \$1.3 million.

The Company has \$7.1 million in cash and cash equivalents as at 30 September 2024, and a further ~\$2.6 million is expected on receipt of the research and development tax offset claim for the financial year ended 30 June 2024.

The Company invested \$0.6 million in the US laboratory during the quarter.

Fees paid to directors for the quarter, being salary, superannuation and consulting fees, amounted to \$194,000.

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  
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## About BCAL Diagnostics

BCAL Diagnostics Limited is an Australian 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. 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**

97 084 464 193

**Quarter ended ("current quarter")**

30 September 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 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	(1,438)	(1,438)
(b) product manufacturing and operating costs		
(c) advertising and marketing	(41)	(41)
(d) leased assets		
(e) staff costs (non R&D)	(291)	(291)
(f) administration and corporate costs	(1,038)	(1,038)
1.3 Dividends received (see note 3)		
1.4 Interest received	51	51
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		
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,757)</b>	<b>(2,757)</b>
<b>2. Cash flows from investing activities</b>	-	-
2.1 Payments to acquire or for:	-	-
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(590)	(590)
(d) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	<b>Net cash from / (used in) investing activities</b>	<b>(590)</b>	<b>(590)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	4,082	4,082
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(113)	(113)
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		
3.10	<b>Net cash from / (used in) financing activities</b>	<b>3,969</b>	<b>3,969</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	6,473	6,473
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,757)	(2,757)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(590)	(590)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,969	3,969
4.5	Effect of movement in exchange rates on cash held		
4.6	<b>Cash and cash equivalents at end of period*</b>	<b>7,095</b>	<b>7,095</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	595	1,973
5.2	Call deposits	6,500	4,500
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,095</b>	<b>6,473</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	194
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 and consulting fees to Directors		

<b>7.</b>	<b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>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		

<b>8.</b>	<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)	(2,757)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,095
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,095
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	2.6
	<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: 31 October 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.