

ASX Announcement

APPENDIX 4C – December 2024 QUARTERLY ACTIVITIES

31 January 2025

- **Preparation nearing completion for launch of BREASTEST® at the Sydney Breast Clinic, with first revenues expected by the end of Q1 CY25.**
- **NATA accreditation received at BCAL's laboratory in North Ryde, Sydney**
- **Publication in highly regarded peer-reviewed journal**
- **Australian patent accepted for BREASTEST®**
- **Received R&D tax offset of \$2.6 million**
- **Cash Balance of \$7.0 Million at end of quarter**

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 2024.

Chief Executive Officer, Shane Ryan commented: "BCAL is on track for the commercial launch of BREASTEST® in Q1 CY25. BREASTEST® will be launched initially at the Sydney Breast Clinic, before the test is rolled out nationally. Achieving medical laboratory accreditation following NATA assessment was an important milestone and a requisite step to prepare the laboratory to bring BREASTEST® to market.

Our achievements have also been validated externally by a highly regarded peer-reviewed journal, International Journal of Molecular Sciences, reinforcing the strength of our mission and technology. The Federal Government's support via the R&D tax incentive further underscores the importance of our work. The road ahead is filled with opportunities, and we remain focused on delivering our unique technology in Q1 CY25 to improve patient outcomes. Our oncologist KOL network continued to grow in Australia and the US which will be invaluable as we deliver our market access plans now, in Australia, and later in the US."

Commercial roll-out

Following the accreditation for our North Ryde laboratory from NATA, BCAL is in the final stages of preparing for its regulatory approval for BREASTEST® and the first commercial site launch at the Sydney Breast Clinic. The test will be offered alongside current screening methods and will begin generating revenues for the Company by the end of Q1 CY25. During this time BCAL will secure partnerships and licencing opportunities to bring BREASTEST® to as many women as possible.

Key appointments

The Company welcomed Dr Mark David as its new Head of Research and Product Discovery who joins BCAL with a wealth of experience in mass spectrometry, lipidomics and metabolomics. With a PhD from Imperial College London, Dr David has experience as a team leader in commercial laboratories and performing ground-breaking research for the discovery of novel diagnostic tests.

NATA accreditation of clinical laboratory

BCAL received formal laboratory accreditation under ISO 15189 (medical laboratories) from the National Association of Testing Authorities, Australia (NATA) on 12 December 2024. The accreditation to this international standard underscores BCAL's commitment to technical excellence and quality management systems required to run a commercial laboratory.

Australian patent accepted for BREASTEST®

BCAL's first self-developed patent, Australian Patent No. 2023258393, titled "Diagnostic signature," has been accepted by IP Australia. Covering key methods and lipids integral to the BREASTEST® technology, the patent is expected to be granted in the near term and will provide IP protection through to 10 May 2043.

BCAL requested accelerated examination of this patent to secure a strong IP protection ahead of the BREASTEST® commercial launch. In addition to this milestone, BCAL now has two self-developed patent families filed internationally via the Patent Cooperation Treaty (PCT). The second patent family was filed on 31 October 2024 and is set for publication within six months.

These filings build on BCAL's existing portfolio of in-licensed patents that includes 23 granted patents and 4 pending patents across jurisdictions including the United States, Australia, Canada, Japan and multiple jurisdictions within Europe.

Publication in highly regarded peer-reviewed journal

During the quarter, an original research article by BCAL was published in the *International Journal of Molecular Sciences*. The article describes the methodology and results from early discovery work that forms the basis of the technology that underpins BCAL's novel blood test for the detection of early-stage breast cancer. Peer-reviewed publications play a key role in gaining commercial and academic validation of new technologies such as BREASTEST®.

The article is titled "Discovery of Plasma Lipids as Potential Biomarkers Distinguishing Breast Cancer Patients from Healthy Controls".

Momentum builds in the US

The US scientific team continues to work seamlessly with the team here in Australia forming a global effort to accelerate product development and discovery of future biomarkers. Sites are preparing for active patient recruitment in Michigan and Chicago, with plans to expand this network and bring a BCAL cancer biomarker to the US market as soon as possible.

In December, CEO Shane Ryan, attended the San Antonio Breast Cancer Symposium (11,000 like-minded delegates) taking the opportunity to share BCAL's progress with industry and senior breast cancer oncologists. There was a great deal of interest from potential strategic industry partners and from breast surgeons who are interested in participating in the recruitment effort for the current US trial.

R&D tax offset received

On 26 November 2024, BCAL confirmed the receipt of its FY2024 Research and Development Tax Incentive (RDTI) tax offset in the amount of \$2.6M. The tax offset is a critical aspect to BCAL funding the development of BREASTEST® and the Company values the strong government support in progressing the commercialisation of breast cancer diagnostic tools like BREASTEST®.

The RDTI is an Australian Government program providing important support for biotechnology and other sectors under which companies receive a refund for eligible expenditure on research and development.

Subsequent to quarter end

Intellectual property

The Company has received notice that the following trademarks are now registered in the United States: BREASTEST®, BCAL Diagnostics® and BCAL Dx®.

Financial performance and cash balance

The Company spent \$2.74M during the quarter which was broadly in line with the plan in order to meet its objectives for the financial year ended 30 June 2025.

The Company paid directors \$0.3M during the quarter which included salaries, fees and a one off bonus of \$0.127M.

The net cash outflow during the quarter was \$0.11M after taking into account the RDTI tax offset amount of \$2.6M.

The cash balance of the Company at the end of the quarter was \$7.1M.

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

ENDS

For further information:

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About BCAL

BCAL 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. The test is initially designed to complement current imaging technologies, such as the mammogram. 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: BDY). 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")

31 December 2024

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	(1,316)	(2,754)
(b) product manufacturing and operating costs		
(c) advertising and marketing	(6)	(47)
(d) leased assets		
(e) staff costs (non R&D)	(44)	(335)
(f) administration and corporate costs	(1,115)	(2,153)
1.3 Dividends received (see note 3)		
1.4 Interest received	28	79
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 received	2,629	2,629
1.9 Net cash from / (used in) operating activities	176	(2,581)
2. Cash flows from investing activities	-	-
2.1 Payments to acquire or for:	-	-
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(259)	(849)
(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	(259)	(849)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)		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)
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 Net cash from / (used in) financing activities		3,969

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	7,095	6,473
4.2 Net cash from / (used in) operating activities (item 1.9 above)	176	(2,583)

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)	(259)	(849)
4.4	Net cash from / (used in) financing activities (item 3.10 above)		3,969
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period*	7,012	7,012

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	1,012	595
5.2	Call deposits	6,000	6,500
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)	7,012	7,095

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	322
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 and consulting fees to Directors and a one off bonus paid to previous CEO (Dr John Hurrell) of \$127,400 (as disclosed in the Annual Report 30 June 2024 as accrued not paid).

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)	174
8.2 Cash and cash equivalents at quarter end (item 4.6)	7,046
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	7,046
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	The Company has greater than two quarters cash based on expenditure in Qtr ended 31 December 2024
<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 January 2025.....

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.