

**ASX Announcement**

27 January 2022

## **APPENDIX 4C – DECEMBER 2021 QUARTERLY ACTIVITIES**

- **Appointment of CEO with excellent global in vitro diagnostics experience**
- **Collection of 290 samples**
- **Agreement with Baker Institute for analysis**
- **Commencement of product development – agreement with Analytical RnD laboratories**
- **Strong Cohort 4 testing data continues to demonstrate value of BCAL test**
- **USA market entry continues to progress – strategic partnerships continue to be explored**

Breast cancer screening and diagnostic company BCAL Diagnostics (ASX:BDX, 'BCAL' or the 'Company') is pleased to present its quarterly activities report for the quarter ended 31 December 2021.

BCAL is developing a non-invasive laboratory blood test for the detection of breast cancer. The core BCAL technology has evolved from extensive research and investment over approximately ten years by BCAL in Australia and independent groups based in the USA, who were able to show that breast cancer patient samples contain significantly different lipid profiles to those of healthy volunteers; using a defined methodology.

BCAL aims initially to launch the test as an in-house developed IVD and use the clinical data generated to support an application to achieve Australian regulatory approval for its breast cancer diagnostic product to complement traditional mammography, seeking to provide physicians with an additional clinical diagnostic tool for more accurate breast cancer detection. The test aims to open new approaches to breast cancer screening, including women who self-exclude for religious or other reasons, noting that mammograms can be painful, uncomfortable, and hard to access.

BCAL continues to implement its business and scientific strategy as outlined in the prospectus for the Company's 2021 IPO, with all key developments and milestones remaining on track to date. This has included the launch of its Australian clinical studies, with various sites collecting blood samples, delivery of strong cohort 4 testing data and the addition of new collaborators.

Subsequent to the end of the quarter, the Company was pleased to announce another of these key milestones, with the appointment of Dr John Hurrell as its Chief Executive Officer. Dr Hurrell will take up the role on 14 February 2022, bringing outstanding global experience in the field of in vitro diagnostics. This includes 7 years in managerial and executive roles with NYSE-listed, Fortune 500 clinical laboratory company Quest Diagnostics. Within Quest's subsidiary Focus Diagnostics, he led the development and launch of more than 70 molecular diagnostics tests and successfully gained 510(k) approvals for 6 products. He also served as VP of Business Development at Quest Diagnostics. Dr Hurrell will divide his time between Australia and the USA, managing the current scientific and clinical activities based in Sydney, while at the same time preparing the Company for future product launch in North America.

The Company made excellent scientific progress during the quarter, collecting a further 190 clinical samples to bring the total to 290. Sydney Breast Clinic, Lifehouse and Breast Screen NSW are all now active, with additional trial sites being considered. To accelerate sample analysis the Company executed an agreement during the quarter with Melbourne's Baker Institute, which will commence sample analysis during Q1 CY2022.

During the quarter BCAL announced that it completed the processing of 301 samples as part of its Cohort 4 testing, with positive results allowing the potential to accelerate development of BCAL's test. The clinical data and results of the combined Cohort 4 and Cohort 3 testing were in alignment with previously reported performance of the test in early-stage detection of breast cancer. Reproducing these results to such a high standard reinforces the continued scientific development and advancement of the science by BCAL's team. The results were based on the 18 candidate lipid marker panel, as previously identified, with pathways to accelerate development of the test showing significant potential.

The product development program commenced during the quarter with the execution of an agreement with Sydney company Analytical RnD. This will effect transfer of the technology into a commercial laboratory and pave the way for the development of an in-house IVD ahead of the pivotal clinical trial and transfer of the test to a commercial laboratory in the USA.

Further progress has been made during the quarter on accelerating market entry into the USA, with the Company planning to execute an agreement for USA sample collection in Q1 CY2022. Discussions with potential partners who can provide BCAL with skills to facilitate scientific development, technical support on product development, and commercial input to market entry in relation to billing and reimbursement assistance, are continuing.

A significant amount of work has been undertaken during the quarter establishing the quality framework for ISO certification policies, procedures and reporting. An ISO audit is planned for Q2 CT2022.

Analysis of cash flow during the quarter is as outlined in the Appendix 4C attached.

Operating cash outflows for the quarter amounted to \$479,000.

A comparison of the cash flow for the half year ended 31 December 2021 with the “use of funds” in year 1 as per the Prospectus lodged with the ASX on 19 July 2021, is as follows:

	<b>Prospectus</b>	<b>Cash</b>	<b>Cash</b>	<b>Cash</b>
	<b>Year 1</b>	<b>Outflow</b>	<b>Outflow</b>	<b>Outflow</b>
		<b>YTD</b>	<b>Quarter 1</b>	<b>Quarter 2</b>
Clinical development	1,500,000	660,216	222,659	437,557
Commercial and product development	400,000	220,306	87,559	132,747
Algorithm development and validation	200,000	-	-	-
Regulatory and intellectual property management	250,000	94,752	1,181	93,571
Working capital	1,000,000	526,747	304,059	222,688
Expenses of the offer	800,000	807,121	807,121	-
GST recoverable	-	-	117,826	(117,826)
R&D tax offset received	-	(289,142)	-	(289,142)
	<b>4,150,000</b>	<b>2,020,000</b>	<b>1,540,405</b>	<b>479,595</b>

Expenditure in the first half year is in line with expectations. Expenses associated with the offer were booked in the first quarter following ASX listing on 21 July 2021.

Use of funds per the prospectus are on an accrual basis whereas the Appendix 4C cash flow report is on a cash basis. Working capital costs for the half year include annual insurance and listing costs, and as a result were greater than the annualised costs pro-rated for the quarter.

Fees paid to directors for the quarter, being salary, superannuation and consulting fees, amounted to \$83,000.

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

ENDS

### Investor & Media Enquiries

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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 91% specificity and 87% accuracy. 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. BCAL has partnered with global integrated cancer care and cardiac provider GenesisCare to conduct clinical research required for regulatory approvals across several jurisdictions, commercialisation and market entry points.

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")**

31 December 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 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	(544)	(854)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (non R&D)	(81)	(94)
(f) administration and corporate costs	(143)	(553)
1.3 Dividends received (see note 3)		
1.4 Interest received		
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	289	289
Costs associated with ASX Listing	-	(207)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(479)</b>	<b>(1,419)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(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)		
<b>2.6 Net cash from / (used in) investing activities</b>		

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)		10,000
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		(600)
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)		
<b>3.10 Net cash from / (used in) financing activities</b>		<b>9,400</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	11,867	3,408
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(479)	(1,419)

Appendix 4C  
**Quarterly cash flow report for entities subject to Listing Rule 4.7B**

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
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)	-	9,400
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>11,388</b>	<b>11,388</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	1,368	1,867
5.2	Call deposits	10,020	10,000
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>11,388</b>	<b>11,867</b>

**6. Payments to related parties of the entity and their  
associates**

- |     |  | <b>Current quarter<br/>\$A'000</b> |
|-----|--|------------------------------------|
| 6.1 | Aggregate amount of payments to related parties and their<br>associates included in item 1 | 83                                 |
| 6.2 | Aggregate amount of payments to related parties and their<br>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

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

**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.*

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000

**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.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(479)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	11,388
8.3 Unused finance facilities available at quarter end (Item 7.5)	
8.4 Total available funding (Item 8.2 + Item 8.3)	11,388
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)*</b>	23.7

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

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

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

## 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: 27 January 2022.....

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.