

APPENDIX 4C - MARCH 2022 QUARTERLY ACTIVITIES

Highlights

- **New independent analysis indicates that a reduced number of markers can be used to distinguish between blood samples of breast cancer patients and normal control samples**
- **Improved prospects for accelerated development and commercial usefulness**
- **New opportunities for patent protection of the test method**
- **Appointment of Dr John Hurrell, who has over 35 years' experience in life sciences and healthcare, as CEO**

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 2022.

BCAL is developing a blood-based test for detection of breast cancer in its early stages. The test is based on disease-associated changes in the profile of lipids (fats) found in blood. As described in the Prospectus for its 2021 IPO, the Company had at that time collected information on blood samples from 3 cohorts of women diagnosed with breast cancer compared with healthy controls. As a result, a panel of 18 different lipids, differing in their amounts between cancer and non-cancer blood samples, had been identified.

Over the past 6 months, samples from a 4th cohort of patients have been examined, bringing the total of samples analysed in Australia since 2018 to 790. Examination of the data from the 4th cohort by the Company's Australian team indicated that a signature with a reduced number of lipid markers than the original 18, as few as 6 to 10, might be sufficient for an effective clinical test. Such a reduction in the number of markers to be examined for each test considerably improves its commercial feasibility and attractiveness, reducing the time, cost and difficulty for analysis of each sample.

Building on the scientific progress made last quarter, in February 2022 BCAL was pleased to report results of analysis of its scientific data carried out independently by its Australian team and by a highly regarded team of international diagnostic experts. BCAL provided scientific data on Cohorts 1, 2, 3, and 4, to be independently reviewed and retrospectively analysed in a strategic collaboration with BSC-Medical ('BSC') from the United States, involving Dr Szilard Voros, and Dr Aruna Bansal. Both experts have a proven track record in developing in vitro diagnostics products (IVDs). The outcome of the analysis by the two teams is that a considerably reduced number of markers, compared with previous information, can be used to distinguish between blood samples of breast cancer patients and normal control samples.

BSC analysed the data in a blinded fashion, without any access to prior in-house results. In this formal analysis conducted pursuant to a pre-specified Statistical Analysis Plan, candidate signatures were developed for five discovery sets. Overall, twelve lipids showing characteristic differences between control and breast cancer samples were selected, with two lipids selected multiple times: lipid 1 (three out of five signatures) and lipid 2 (four out of five signatures). These signatures delivered strikingly consistent performance and are in agreement with BCAL's local blind testing findings.

An in-house comparison of the 12 lipids identified by Dr Bansal to BCAL's results showed a 50% overlap despite the use of very different approaches. Furthermore, the 2 lipids in the most promising signatures identified by Dr Bansal are part of BCAL's 18 lipid panel and 2 of the 12 are part of BCAL's locally optimised 6-lipid signature. This is a significant outcome given that the 12 lipids were identified out of 400+ candidates and half of them were mutually identified.

The combination of these local and international analyses supports BCAL's goal of reaching a refined algorithm, facilitating acceleration of test development in a format that will be attractive both clinically and commercially. In addition, this greater refinement of the lipid marker panel has opened up the opportunity for BCAL to secure additional patent protection for its test.

The new independent review provides the Company with strong assurance in advancing the test's development towards commercial use and the Company is accelerating its program of moving the test into a commercial laboratory in Australia and the USA.

Earlier in the quarter, experienced life science and healthcare executive Dr John Hurrell was appointed as the Company's Chief Executive Officer (CEO), commencing 7 February 2022. Dr Hurrell has developed and successfully commercialized multiple products and services in life sciences and diagnostics over a career in the industry spanning more than 35 years. He has developed and managed start-up and early-stage companies including successful life science companies based on university-developed technologies.

Dr Hurrell spent almost 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.

Most recently, he was Chief Commercial Officer at JanaCare, a remote chronic disease patient management company with a focus on diabetes and kidney disease.

Other previous roles include President of the Asia/Pacific region and Head of International Sales for PTS Diagnostics, a diabetes and wellness company based in Indiana, USA, and Senior Executive Vice President International Business for Seegene Inc., a multinational molecular diagnostics company focusing on infectious disease, based in Seoul, South Korea.

Dr Hurrell's strong track record in starting, building and improving the profitability, performance and value of life science and healthcare companies will be key to BCAL as the Company continues to drive development of our technology to provide early and accurate breast cancer diagnosis to improve outcomes for patients.

During March BCAL released a shareholder newsletter with a range of information, recaps and updates from the Company. The newsletter can be viewed on the BCAL website at:

https://www.bcaldiagnostics.com/files/ugd/519490_55caefb42d2c4eb6976ca200cee26f48.pdf

Analysis of the cash flow during the quarter is as outlined in the Appendix 4C attached, with a summary outlined below.

Operating cash outflows for the quarter amounted to \$694,000. A comparison of the cash flow for the nine months ended 31 March 2022 with the “use of funds” in year 1 as per the Prospectus lodged with the ASX on 19 July 2021, is as follows:

	Prospectus	Cash	Cash Outflow	Cash Outflow	Cash Outflow
	Year 1	YTD	Quarter 1	Quarter 2	Quarter 3
Clinical development	1,500,000	976,216	222,659	437,557	316,000
Commercial and product development	400,000	280,306	87,559	132,747	60,000
Algorithm development and validation	200,000	20,000	-	-	20,000
Regulatory and intellectual property management	250,000	125,752	1,181	93,571	31,000
Working capital	1,000,000	792,747	304,059	222,688	267,000
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)	-
	4,150,000	2,714,000	1,540,405	479,595	694,000

Expenditure in the first nine months 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.

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

Matthew Wright
 NWR Communications
matt@nwrcommunications.com.au
 +61 451 896 420

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 March 2022

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	(445)	(1,300)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (non R&D)	(54)	(148)
(f) administration and corporate costs	(195)	(748)
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
Costs associated with ASX Listing	-	(207)
1.9 Net cash from / (used in) operating activities	(694)	(2,114)

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)		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)		
3.10 Net cash from / (used in) financing activities		9,400

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	11,388	3,408
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(694)	(2,114)

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)	-	9,400
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	10,694	10,694

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	1,674	1,867
5.2	Call deposits	10,020	10,000
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)	10,694	11,867

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	83
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.

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<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>		
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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(694)
8.2 Cash and cash equivalents at quarter end (item 4.6)	10,694
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	10,694
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	15.4
<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	
<i>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.</i>	

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: 28 April 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.