

ASX Announcement

16 January 2023

APPENDIX 4C – DECEMBER 2022 QUARTERLY ACTIVITIES REPORT

- **Established development & clinical services laboratory**
- **Significant advances in commercialising test**
- **Research and development tax offset of \$876k received**
- **Accelerated financial spend compared with prospectus, reflects achievement of milestones**
- **Cash at 31 December 2022 – \$6.8 million**

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 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. BCAL's breast cancer test (BCAL Dx) has consistently shown high sensitivity and specificity in identifying patients and will supplement mammography, the current primary method for breast cancer screening. Market intelligence currently shows up to 50% of women do not get mammography, where sensitivity and specificity varies dramatically by radiologist, and which is less effective in detecting disease in the early stage.

BCAL development and clinical service laboratory

To accelerate market access for the BCAL test the Company, during the quarter, executed a lease for a Sydney facility that will be the Development and Clinical Services Laboratory for the Company and appointed Ms Kathy Koskiris as Director of this new laboratory. Ms Koskiris has managed the Quality Management Systems required to be compliant with ISO 15189, NPAAC (National Pathology Accreditation Advisory Council) certifications and requirements of the Australian Therapeutic Goods Act, and has managed an Australian laboratory to be compliant and attain the US CLIA High Complexity laboratory certification.

Achieving these accreditations will allow the BCAL breast cancer blood test to be available to the medical community and patients as an in-house developed test, also known as an LDT. Patient samples will be collected and forwarded to this laboratory where they will be tested for the proprietary BCAL lipid signature that is indicative for breast cancer.

This is a major step towards the commercialisation of the Company's blood-based test to detect breast cancer. The laboratory will utilise the findings of the Company's clinical studies to date and the outcomes of work being carried out by BCAL's US commercialisation partner Precion Inc. to establish, validate the workflow and test protocols for the BCAL breast cancer test. Precion has made excellent progress during the quarter in the development of internal reference standard lipids in-house and the development of an optimised, cost effective assay procedure. In addition, BCAL has made progress in the identification of sites for sample collection in the US and developed clinical protocols required for US clinical studies.

Significant advances in commercialising test

BCAL made significant advances during the quarter towards commercialising the test. The Company has validated the most simple efficient method for collecting samples and is currently trialing 'patient sample to test' flowsheet alternatives to determine the optimum commercial process.

Significant advances using Artificial Intelligence (AI) and Machine Learning (ML) techniques have been made in identifying the optimal lipid signature and identifying an individual patient against this signature with consistent results, on a small sample number, showing sensitivity at 91.5% and specificity at 80%. These results are being confirmed on a larger and more diverse data set.

The Company has completed its first assessment of intended use, and research into target market and development of financial models is ongoing. Focus groups with representatives of all major stakeholders in the diagnosis and treatment of breast cancer were held in Melbourne and Sydney to assist in the development of the strategy for BCAL to enter the market in Australia. The outcomes will be further tested in additional studies. A review of the US payor and reimbursement system has been completed by the Boston based market research firm Veranex. This study included direct discussions with major US health insurance companies and stakeholders in the US breast cancer market.

Research and development tax offset

The Company is pleased to advise that the Australian Taxation Office (ATO) has recognised the innovation of the research and development, resulting in BCAL receiving the Research and Development tax offset of ~\$876,000 in respect of the 30 June 2022 financial year, during the quarter.

The Company was successful in its Advance/Overseas finding application for the financial years 2022, 2023 and 2024. This enables the Company to claim the tax offset research and development expenses incurred overseas, for research work that is not able to be undertaken in Australia.

The Research and Development Tax Incentive scheme is a program jointly administered by the ATO and AusIndustry, under which companies can receive up to a 43.5% refundable tax offset of eligible expenses on research and development activities.

Financial performance

Operating cash outflows for the quarter amounted to \$1,076,000 (after the receipt of a Research and Development tax offset in the amount of \$876,000 in respect of the year ended 30 June 2022). A comparison of the cash flow for the year ended 30 June 2023 with the “use of funds” in year 2 as per the Prospectus lodged with the ASX on 19 July 2021, is as follows:

	FY 2022 Prospectus Year 1	Cash Outflow Year 1	FY 2023 Prospectus Year 2	Cash Outflow Q1&2 Year 2
Clinical development	1,500,000	1,549,000	1,900,000	2,273,000
Commercial and product development	400,000	372,000	600,000	427,000
Algorithm development and validation	200,000	20,000	100,000	54,000
Regulatory and intellectual property management	250,000	259,000	250,000	116,000
Working capital	1,000,000	1,149,000	1,000,000	766,000
Expenses of the offer	800,000	807,121	-	-
R&D tax offset received	-	(289,142)	-	(876,000)
	4,150,000	3,866,979	3,850,000	2,760,000

Expenditure in Q1 and Q2 FY2023 (year 2 vs prospectus) reflects an acceleration of activity as the Company targets the release of the BCAL blood test for breast cancer by the end of the 2023 calendar year. The acceleration in the US is particularly important given the size of the market and the diversity of the population. The early commitment to the laboratory in Australia has also contributed to increased cost.

Expenditure in the first twelve months to 30 June 2022 (year 1 vs prospectus) was in line with expectations. Expenses associated with the offer were booked in the first quarter following ASX listing on 21 July 2021, with part of these costs having been prepaid in the 2021 financial year.

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 \$98,000.

This ASX Quarterly Activities Report has been approved for release by the Board of BCAL Diagnostics Limited.

ENDS

Jayne Shaw

Executive Chair

Jshaw@bcaldiagnostics.com

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% sensitivity and 80% specificity. 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 Precion Inc. to optimise protocols and procedures for the clinical studies 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/>

About Precion Inc

Precision applies mass spectrometry technology to develop and provide targeted metabolite panels for profiling various chronic disease conditions and associated health areas for clinical research. Precision offers development of diagnostics and precision medicine assay formats for downstream applications. Our testing services for commercial and research customers provides data for various sample types and project objectives. We offer a range of targeted panels as well as custom developed panels for partners with specific clinical objectives. For more information: <https://www.precion.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 2022

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	(1,658)	(2,900)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (non R&D)	(92)	(160)
(f) administration and corporate costs	(185)	(569)
1.3 Dividends received (see note 3)		
1.4 Interest received	23	32
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	876	876
1.9 Net cash from / (used in) operating activities	(1,036)	(2,721)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(39)	(39)
(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	(39)	(39)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
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		
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		

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,886	9,571
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,036)	(2,721)

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)	(39)	(39)
4.4	Net cash from / (used in) financing activities (item 3.10 above)		
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	6,811	6,811

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	791	866
5.2	Call deposits	6,020	7,020
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)	6,811	7,886

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	98
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>		

7. Financing facilities <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>	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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,036)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,811
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,811
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.6*
<i>*excluding the R&D tax offset received during the quarter the Company has 3.6 quarters of funding availab/e</i>	
<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: 16 January 2023.....

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.