

ASX Announcement

28 July 2022

APPENDIX 4C – JUNE 2022 QUARTERLY ACTIVITIES

- **Strong progress in establishing resources in US to accelerate progress to commercialisation**
- **Filing of provisional patent application**
- **Product development agreement executed with Precion**
- **Presentation at American Society of Clinical Oncology (ASCO)**
- **Financial performance in line with prospectus**
- **Cash at 30 June 2022 – \$9.6 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 30 June 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 a mammography, where sensitivity and specificity varies dramatically by radiologist, and which is less effective in detecting disease in the early stage.

To accelerate BCAL bringing its test to market it is simultaneously working on completing studies and finalising performance parameters for BCAL Dx in the laboratory and transferring the test to a commercial laboratory. This includes developing this capacity in the US, providing access to an ethnically diverse sample base not accessible in Australia.

BCAL has made strong progress during the quarter in building the capacity in the US with the appointment of Dr David Peake (Scientific Lead, Technology Transfer) who will manage the relationship with US partner, Precion Inc. (Precion), and Brian Kolasinski (Business Strategy and Development) to assist in determining the viability and go-to-market strategy of potential avenues for revenue generation. These may include:

- Development and launch of a proprietary diagnostic test for breast cancer
- Partnership with existing cancer diagnostic and cancer therapeutic companies
- Partnership with healthcare provider networks

In May, BCAL announced the filing of a provisional patent application at IP Australia covering key lipid biomarkers that form part of its revolutionary blood-based breast cancer diagnostic. The patent application covers the detection of a number of key biomarkers in the diagnosis of breast cancer and provides the option to build a patent portfolio covering several aspects of BCAL's test. This initial filing in Australia will form the basis of multiple patent applications to be entered into within selected international markets as BCAL enhances its patent portfolio. The patent application is based on rigorous statistical analysis of multiple patient cohorts having various subtypes and stages of breast cancer. Each patient's blood lipid profile has been interrogated and the BCAL team's analysis of the aggregate results has revealed a striking selection of specific lipids having important diagnostic power.

Late in the quarter BCAL entered into an agreement with US company Precion for the next stage of development of the Company's blood-based test to detect breast cancer. The move marks an important milestone as BCAL aggressively works to commercialise this valuable product and make it available to women.

The Company's US-based and Sydney-based teams are now working directly with Precion's North Carolina laboratories in the development of standardised commercial assays. The assays will be based on the proprietary lipid biomarker signature BCAL identified in the blood samples of early and late-stage breast cancer cohorts. The parties have signed a Master Services Agreement under which they have executed the first Statement of Work to collaborate in the development of standardised biomarker tests, validate the algorithm required for reporting results and carry out clinical studies in the US.

Precision brings together the most advanced technology and an experienced team of scientists with a track record of successfully developing and validating commercial biomarker assays using Mass Spectrometry. The instrumentation

utilised by the Precion team will be similar to that currently available in clinical laboratories. The work will also facilitate similar technology transfer and validation activities being established with laboratories in Sydney.

BCAL presented at the ASCO Annual Meeting in Chicago in June 2022, a paper titled "Detection of early-stage breast cancer in women by plasma lipidomic profiling". The meeting was attended by more than 40,000 oncology professionals where clinical advances in every area of cancer research are discussed and presented.

Clinical Associate Professor Gillian Lamoury of the University of Sydney, also Radiation Oncologist at GenesisCare, and BCAL's Chief Scientific Officer Dr Amani Batarseh presented BCAL's poster in the Breast Cancer-Local/Regional/Adjuvant session.

Operating cash outflows for the quarter amounted to \$1,153,000. A comparison of the cash flow for the year ended 30 June 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 Year 1	Cash Outflow YTD	Cash Outflow June Quarter
Clinical development	1,500,000	1,549,000	573,000
Commercial and product development	400,000	372,000	92,000
Algorithm development and validation	200,000	20,000	-
Regulatory and intellectual property management	250,000	259,000	133,000
Working capital	1,000,000	1,149,000	355,000
Expenses of the offer	800,000	807,121	-
GST recoverable	-	-	-
R&D tax offset received	-	(289,142)	-
	4,150,000	3,866,979	1,153,000

Expenditure in the first twelve 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

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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/>

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")

30 June 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(798)	(2,097)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (non R&D)	(78)	(226)
(f) administration and corporate costs	(277)	(1,026)
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	(1,153)	(3,267)

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 (12 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	30	30
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	30	9,430

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	10,694	3,408
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,153)	(3,267)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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)	30	9,400
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	9,571	9,571

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	551	1,674
5.2	Call deposits	9,020	10,020
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)	9,571	10,694

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	
<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)	(1,153)
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,571
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,571
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	8.3
<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 July 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.