

ASX Announcement

27 July 2023

APPENDIX 4C – JUNE 2023 QUARTERLY ACTIVITIES REPORT

- **New laboratory opening with Liquid Chromatography Mass Spectrometry (LCMS) platforms operational**
- **Precision in US completes LCMS analysis on 656 samples**
- **BCAL in discussions relating to using its lipidomics platform to analyse other cancers**
- **Two year spend, net of R&D tax offset in line with prospectus at ~\$10 million**
- **Cash at 30 June 2023 – \$3.2 million, with an R&D tax offset claim of ~\$2.5 million in progress**

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 2023.

BCAL is developing a blood-based test for screening for breast cancer in its early stages which will initially be used alongside other screening methods. The test is based on disease-associated changes in the profile of lipids (fats) found in blood. BCAL's 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 eligible for do not get mammography, where sensitivity and specificity varies dramatically by radiologist and by women's physiology, and which is less effective in detecting disease in its early stages and in younger women. BCAL continues to work with leading breast cancer radiologists, surgeons, and oncologists to guide the development and commercial strategy for the breast cancer blood test.

BCAL development and clinical service laboratory opened

BCAL's development and clinical service laboratory was officially opened in early May 2023.

The laboratory is utilising the latest Liquid Chromatography Mass Spectrometry (LCMS) platforms to continue to advance the findings of the Company's clinical research to-date and the progress made by BCAL Diagnostics' US commercialisation partner, Precision Inc. to establish and validate workflows, test protocols and algorithms for the BCAL blood screening tool.

BCAL has purchased an Exploris 240 LCMS machine which has now completed performance and validation checks. In addition the Company has on loan from the supplier a TSQ Altis Plus QQQ machine (used by Precision) to enable BCAL to validate the Precision results.

The BCAL laboratory will also serve as the testing site for the ongoing and planned clinical validation studies and will establish the quality systems and protocols to be compliant with ISO 15189, CLIA accreditation, NPAAC (National Pathology Accreditation Advisory Council) certifications and requirements of the Therapeutic Goods Act 1989 (Cth).

BCAL's first commercial milestone is for its blood-based test to be available to the medical community as an additional tool to facilitate clinical decisions by the physician, in Australia.

Precision in US completes LCMS analysis of 656 samples.

Precision, BCAL's partner in the US, has now completed the LCMS analysis of 656 plasma samples provided from Australia and Europe, using their newly developed analytical method, to provide quantitative results on each of the identified lipid signatures.

This data has been forwarded to Sydney for statistical analysis, and the lipid extracts have been sent to BCAL for comparison analysis between the BCAL TSQ Altis LCMS and the similar LCMS used by Precision. Getting the same results on different LCMS machines will be an important point for transfer of the BCAL test to various pathology labs in the future.

The results from the Precision analysis are eagerly awaited as this will provide substantial third-party confirmation of the BCAL test.

BCAL in discussions relating to using its lipidomics platform to analyse other cancers

BCAL is continuing discussions with global leaders in other areas of cancer research, to potentially use its lipidomics platform to assist in the early detection of conditions such as prostate, ovarian and brain cancer.

These collaborations have the potential to initially increase the number and reduce the costs of samples required to further analytical studies and in the longer term broaden BCAL's commercial revenue base.

During the quarter BCAL appointed Mr. David Darling as an advisor to the Company. For the past 19 years, Mr. Darling was previously CEO of Pacific Edge, a NZX50 business focused on commercialising its bladder cancer diagnostics tests in global markets, particularly the USA. Mr. Darling has a background as a scientist, with a specialty in genetics, and has more than three decades experience in developing and commercialising life sciences and biotechnology products businesses.

In further recognition of BCAL's progress towards developing a non-invasive blood screening test using a plasma lipidomic biomarker signature, Dr Gillian Lamoury presented on behalf of BCAL at the June 2023 American Society of Clinical Oncology meeting. The presentation demonstrated that using blood plasma reduced the complexity and advanced the commercial viability of the BCAL test.

Financial performance

Operating cash outflows for the quarter amounted to \$1.984m. Cash on hand as of 30 June 2023 is \$3.2m. 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 (and as adjusted for a \$10m IPO capital raise, is as follows:

	FY 2022 Prospectus Year 1	Cash Outflow Year 1	FY 2023 Prospectus Year 2	Cash Outflow Q1,2&3 Year 2
Clinical development	2,250,000	1,549,000	2,650,000	4,268,000
Commercial and product development	600,000	372,000	800,000	1,427,000
Algorithm development and validation	200,000	20,000	100,000	106,000
Regulatory and intellectual property management	250,000	259,000	250,000	280,000
Working capital	1,000,000	1,149,000	1,000,000	1,345,000
Expenses of the offer	900,000	807,121	-	-
R&D tax offset received	-	(289,142)	-	(976,000)
	5,200,000	3,866,979	4,800,000	6,449,000

Expenditure in the year to 30 June 2023 reflects an acceleration of activity as the Company targets the release of the BCAL blood-based test. For the two years ended 30 June 2023 the combined spend is \$11.6 million or \$10.3 million after receipt of the Research and Development tax offset for the 2021 and 2022 financial years. This compares to a prospectus projection of \$10 million.

The Company is currently preparing the FY23 Research and Development tax offset claim which it expects to be approximately \$2.5 million.

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

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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 90% sensitivity and 85.5% 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.

Founded in 2010, BCAL is headquartered in Sydney and listed on the Australian Securities Exchange (ASX: BDJ). 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 provide data for various sample types and project objectives. We offer a range of targeted panels and 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 2023

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	(1,757)	(5,973)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs (non R&D)	(161)	(466)
(f) administration and corporate costs	(181)	(876)
1.3 Dividends received (see note 3)		
1.4 Interest received	14	72
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	101	977
1.9 Net cash from / (used in) operating activities	(1,984)	(6,266)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(122)	(181)
(d) investments		

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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	(122)	(181)

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	50	50
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	50	50

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,230	9,571
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,984)	(6,266)

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)	(122)	(181)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	50	50
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,174	3,174

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	1,023	1,210
5.2	Call deposits	2,151	4,020
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)	3,174	5,230

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	

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.

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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,984)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,174
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	3,174
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.6
<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: Cash outflows during the quarter included substantial costs relating to the laboratory set up. As a consequence, operating cash outflows in the upcoming quarter will be lower.	
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: The Company will have a material research and development tax offset claim in respect of the 2023 financial year, currently estimated at \$2.5 million.	
The Directors believe the Company should be in a position to raise capital as and when required.	

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: Yes, funds on hand, lower upcoming operating costs, research and development tax offset receivable, capital raise as and when required.

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: 27 July 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.