ASX Announcement
31 October 2023

APPENDIX 4C – SEPTEMBER 2023 QUARTERLY ACTIVITIES REPORT

- **Excellent clinical correlation between internal validation studies conducted in Sydney and the USA using a large (656) cohort of clinical samples.**
- **Precion result indicates the robust nature of the BREASTEST™ and enables blood samples to be analysed in many commercial laboratories worldwide, fast-tracking market access and penetration.**
- **Pre-analytical studies are establishing important requirements for sample processing and tolerable limits.**
- **Recruitment of a cancer market specialist, Shane Ryan, as Chief Operating Officer.**
- **Medical Advisory Board has been formed to assist the company in clinical utility decisions.**
- **Successful capital raise of $3 million completed through share placement and share purchase plan.**

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 September 2023.

BCAL is developing a blood-based test for detection of early-stage breast cancer. The test, BREASTEST™ is based on disease-associated changes in the profile of lipids (fats) found in blood. BCAL's BREASTEST™ (BCAL Dx) has consistently shown high sensitivity and specificity in detecting the occurrence of breast cancer and will supplement mammography, the current primary method for breast cancer screening. Market intelligence currently shows up to 50% of women above the age of 30 do not get a mammogram, where sensitivity and specificity varies dramatically by radiologist, and which is less effective in detecting disease in the early stage.

Significant Scientific Progress

In this quarter BCAL announced breakthrough results[1] from a clinical study it sponsored with Precion Inc. in North Carolina, US ("Precion"). The analysis undertaken achieved an impressive sensitivity of 90% and a specificity of 85.5% in internal validation studies involving 656 samples, collected and processed according to the BCAL protocol, from breast cancer patients and healthy control subjects. These results were consistent with the findings of earlier studies conducted in Australia using a different mass spectrometry platform. This validation shows strong potential performance with a balance of sensitivity (ability to detect true positive samples) and specificity (ability to detect true negative samples).

This study indicates the robustness of the BCAL breast cancer plasma lipid signature and the transferability of the test between laboratories and instrument types. The initial BCAL research was conducted with high sensitivity research instrumentation while the Precion results were obtained with instrumentation and procedures in routine use in clinical laboratories. The replication of these results between laboratories and instrument types is a major breakthrough in the path to commercialisation of the BCAL test. These results enhance the confidence of the Company that the BCAL blood-based test for detecting breast cancer will be available for commercial sales, for use in conjunction with mammograms, in the second half of calendar 2024.

The Company continues to carry out analysis of the data generated in this sentinel study and has locked down the identity of the 20 lipids that comprise the signature for detecting breast cancer in the samples tested. Further analysis is showing that all 20 of the lipids may not be required and the presence of breast cancer can be identified with a smaller number of lipids within the key 20 lipids. This will be important in reducing the complexity and cost of the test as we optimise the product for commercial release.

BCAL scientists made oral presentations and posters relating to the BCAL science and clinical results at the American Association of Clinical Chemists AACC), in Anaheim CA., the Australasian Association for Clinical Biochemistry and Laboratory Medicine (AACB), and subsequent Chromatography and mass spectrometry satellite meeting in Brisbane. The BCAL Product Development Leader, Dr Ameline Lim won the award for the best oral presentation at the satellite meeting. These presentations are important to raise the profile of BCAL's work and to achieve interest in and acceptance of the test in scientific and clinical communities, a vital step in achieving market share for BREASTEST™ when it is made available for clinical use.

[1] See ASX announcement 2 August 2023: Breakthrough Results a Major Step Towards Commercialisation.

Optimisation of Pre-analytical Blood Processing

Clear instructions for collection, transportation, and processing of patients' blood prior to testing are important to ensure results obtained are accurate and consistent. Understanding the tolerable variation in different steps of collection and processing is important for the development of a commercial test. During this last quarter, BCAL has been studying the times and temperatures for the different steps along the sample processing route. Results indicate that the test is remarkably robust and further studies are underway to develop limits of tolerance for each step.

Key Recruitment Success

During this quarter we recruited Mr Shane Ryan to the position of Chief Operating Officer[2]. Shane joins BCAL from GenesisCare where he was most recently the Global Senior Vice President Strategy & Innovation – Patient Access. Shane has more than 20 years' experience in the global oncology market and in particular breast cancer. He has an extensive Oncology network and deep understanding of what is critically important to both cancer patients, their treating Oncologist, and the extended multidisciplinary team. His experience covers patient care, research, innovative service delivery models, and commercial aspects of cancer patient management. Prior to joining GenesisCare, Shane spent 10 years with globally recognised Peter MacCallum Cancer Centre where he held Executive positions in Clinical Operations, Services Development and Surgery. Shane is focusing particularly on the clinical aspects of the BCAL test development. He has already established a formal Clinical Advisory group of leading national breast cancer clinicians in order to guide the clinical utility of the BREASTEST™.

Sample Collection

The collection of samples from breast cancer patients is critical to the development of the BCAL test. The Company collects samples and includes important medical and personal history from each patient according to a protocol that has both Ethics and Governance approval. Prospective sample collection mimics how the test will be run in the clinics and allows us to control the sample through the process from collection to result determination. The company has collected over 2,500 samples from biopsy-confirmed breast cancer patients and healthy controls from Europe, Australia, and the USA, including over 600 samples collected in this past Quarter, with 9% positive for breast cancer, from Australian women. This high collection rate was possible due to the cooperation and enthusiasm for the BCAL test by the clinicians in major cancer care centers in Sydney and Melbourne. Large numbers of diverse samples are important in the development of Machine Learning (a form of artificial intelligence, AI,) models that in the BCAL case provides the mathematical algorithm for the lipid signature used to determine the presence or absence of breast cancer.

Clinical Services Laboratory Progress

When accreditations by the National Association of Testing Authorities (NATA) under the ISO 15189 requirements and National Pathology Accreditation Advisory Council (NPAAC) certifications are achieved for the BCAL Clinical Services Laboratory, they 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, processed, and forwarded to this laboratory where they will be tested for the proprietary BCAL lipid signature that is indicative for breast cancer. This Quarter progress was made on the implementation of the Quality Management System required for accreditation and preparations were commenced in readiness for a scheduled advisory visit by NATA inspectors in November 2023.

Advocacy and Partnerships

In July, Associate Professor Sanjay Warrior, a well-known Sydney breast surgeon, presented a paper at the Breast Cancer Trials 44th Annual Scientific Meeting in Auckland. The paper discussed BCAL's scientific updates and how BREASTEST™ could fit within the screening process.

The Company has also continued to develop strong partnerships with breast cancer advocacy groups such as SoBrave, Sydney Breast Cancer Foundation and Pink Hope. These organisations represent women with known high risk for breast cancer and their members are supporting the BCAL efforts in making the BREASTEST™ available as soon as possible specifically by providing blood samples. These are important samples as the cohort of patients with a known high risk is one of the initial intended use populations for the test.

[2] ASX announcement 2 September 2023: Shane Ryan appointed Chief Operating Officer.

Financial report

Capital raising

The Company was successful during the quarter in raising ~$3 million, before costs, through the issue of 29,855,000 shares at $0.10 per share, in a share placement and share purchase plan. A further 917,832 shares were issued on exercise of options at $0.0574 per share for ~$53k.

Financial performance

Research and development costs for the quarter were ~$1.6 million and were consistent with operations as the Company moves to getting the BREASTEST™ product to market in 2024. The costs included the final major costs of Precion as this part of the program was completed and the costs of IT infrastructure and systems to support the laboratory.

Administration costs for the quarter at $0.48 million were higher than normal as they included a number of annual costs including insurance, ASX fees and indirect costs associated with the capital raising.

The Company has completed and filed the FY23 Research and Development tax offset claim estimated at approximately $3.0 million, with receipt expected in Q2 FY 2024.

The Company has $3.6 million in the bank as at 30 September 2023.

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: 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	**Quarter ended ("current quarter")**
97 084 464 193	30 September 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(1,578)	(1,578)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs (non R&D)	(107)	(107)
	(f) administration and corporate costs	(480)	(480)
1.3	Dividends received (see note 3)		
1.4	Interest received	4	4
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		
1.9	**Net cash from / (used in) operating activities**	**(2,161)**	**(2,161)**

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 (3 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)	2,765	2,765
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	53	53
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(198)	(198)
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**	**2,620**	**2,620**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,174	3,174
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,161)	(2,161)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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)	2,620	2,620
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**3,633**	**3,633**

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	2,632	1,023
5.2	Call deposits	1,001	2,151
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)**	**3,633**	**3,174**

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** *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.*	**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)	(2,161)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,633
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,633
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.6

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.

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 include a number of annual costs for insurance, ASX, and closing Precion costs.

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 $3.0 million which should be received in Q2 FY 2024.

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: 31 October 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.