

23 February 2022

The Company Announcements Office
Australian Securities Exchange Limited
Sydney NSW

Appendix 4D – Half Year Report

1.	Name of Entity	BCAL Diagnostics Limited
		ABN 51 142 051 223
	Half year ended	31 December 2022
	Reporting period	1 July 2021 to 31 December 2022
	Previous period	1 July 2021 to 31 December 2021

2. Results for announcement to the market

	31 December 2022	31 December 2021	% Change Up (Down)
2.1 Revenues from continuing operations	1,007,638	409,334	+246%
2.2 Loss from operations after tax attributable to members	(2,470,920)	(1,316,238)	(88%)
2.3 Net loss attributable to members	(2,470,920)	(1,316,238)	(88%)
2.4 Proposed dividends	Nil	Nil	
2.5 Record date for determining dividend	N/A	N/A	
2.6 An explanation of the above figures is contained in the “Review of Operations” included within the attached directors’ report.			

	31 December 2022	31 December 2021	% Change Up (Down)
3. Net tangible asset per security	0.036 cents	0.056 cents	(36%)

4. Details of entities over which control has been gained or lost during the period.
NIL



For personal use only

5. There were no payments of dividends during the reporting period.
6. There is no dividend reinvestment plan in operation.
7. There are no associates or joint venture entities.
8. The Company is not a foreign entity.
9. The accounts are not subject to any audit dispute or qualification.

The Company's half year report follows.

For more information, please contact:

BCAL Diagnostics Limited

Jayne Shaw | Executive Chair

jayneshaw@bcaldiagnostics.com

Mr Guy Robertson | Company Secretary

guyrobertson@bcaldiagnostics.com

About BCAL Diagnostics Limited (BCAL)

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 from different trials to date demonstrating up to 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/>



BCAL Diagnostics Limited ABN 51 142 051 223

Suite 506, Level 5, 50 Clarence Street, Sydney NSW 2000

T +61 (0) 407 983 270 **W** www.bcaldiagnostics.com **E** info@bcaldiagnostics.com



BCAL Diagnostics Limited

ABN 51 142 051 223

Interim Report – 31 December 2022

For personal use only

BCAL Diagnostics Limited
Financial Report
For the half year ended 31 December 2022

Table of Contents

	Page
Directors' Report	3
Auditor's Independence Declaration	5
Condensed Statement of Profit or Loss and Other Comprehensive Income	6
Condensed Statement of Financial Position	7
Condensed Statement of Changes in Equity	8
Condensed Statement of Cash Flows	9
Notes to the Financial Statements	10
Directors' Declaration	13
Independent Auditor's Report to the Members	14

For personal use only

BCAL Diagnostics Limited
Director's Report
For the half year ended 31 December 2022

The Directors' of BCAL Diagnostics Limited ("BCAL" or "Company") present their report, together with the financial statements, for the financial half-year ended 31 December 2022.

Directors

The following persons were directors of the Company during the whole of the financial half-year and up to the date of this report, unless otherwise stated:

Jayne Andrea Shaw	Executive Chair
Ronald Anthony Phillips	Non-executive Director
Jonathan Alfred Trollip	Non-executive Director
Merilyn Sleigh	Non-executive Director
Mark Burrows	Non-executive Director

Principal activities

During the financial half-year the principal continuing activities of the Company consisted of continuing research into the development of a novel blood screening test to improve the early diagnosis and monitoring of breast cancer including preparation for clinical trials.

Review of Operations

The loss for the financial half year ended 31 December 2022, after tax, amounted to \$2,470,920 (2021: loss \$1,316,238).

The Company has no trading revenue at present and the result reflects the research and development activities for the period.

BCAL is developing a non-invasive laboratory blood test for the detection of breast cancer. The core BCAL technology has evolved from extensive research and investment over approximately ten years by independent groups based in the USA and Australia, who were able to show that breast cancer patient samples contain significantly different lipid profiles from those of healthy volunteers using a defined methodology. Furthermore, and independently, a team at University of Louisville showed a difference between lipid profiles from breast cancer and lung cancer patients.

During the half year, BCAL has made significant progress towards commercial development, and ultimately sales, of its blood-based breast cancer test.

To accelerate market access for the BCAL test the Company has now executed a lease for a Sydney facility that will be the Development and Clinical Services Laboratory for the Company and appointed a Director of this new laboratory. The laboratory will be the testing site for the ongoing and planned clinical studies and will establish the quality systems and protocols to be compliant with ISO 15189, NPAAC (National Pathology Accreditation Advisory Council) certifications and requirements of the Australian Therapeutics Good Act.

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.

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 half year in the development of internal reference standard lipids in-house and the development of an optimised, cost effective

BCAL Diagnostics Limited
Director's Report
For the half year ended 31 December 2022

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.

The Company has also 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 for a cost-effective test.

Significant advances using Artificial Intelligence (AI) and Machine Learning (ML) techniques have been made in identifying the optimal lipid signature. It is now possible to test an individual patient sample against this signature identifying whether the sample is breast cancer positive or negative. On a small sample number, using plasma directly, BCAL tests are showing sensitivity at 91.5% and specificity at 80%. These results are now being confirmed on a larger and more diverse sample 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.

Significant changes in the state of affairs

There were no significant changes in the state of affairs of the Company during the financial half year.

Significant events after balance sheet date

There are no matters or circumstances that have arisen since the end of the financial period that have significantly affected or may significantly affect the operations of the Company, the results of those operations, or state of affairs in future financial years.

Rounding of amounts

In accordance with ASIC Corporations (Rounding in Financial/Director's Reports) Instrument 2016/191, the amounts in the directors' report and in the financial report have been rounded to the nearest dollar, unless otherwise stated.

Auditor's Independence

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on page 5.

Signed in accordance with a resolution of the directors.



Jayne Shaw
Executive Chair
23 February 2023

Pitcher Partners Sydney Partnership

Level 16, Tower 2 Darling Park
201 Sussex Street
Sydney NSW 2000

Postal Address
GPO Box 1615
Sydney NSW 2001

p. +61 2 9221 2099
e. sydneypartners@pitcher.com.au

**Auditor's Independence Declaration
To the Directors of BCAL Diagnostics Limited
ABN 51 142 051 223**

In relation to the independent auditor's review for the half-year ended 31 December 2022, to the best of my knowledge and belief there have been:

- (i) no contraventions of the auditor independence requirements of the *Corporations Act 2001*; and
- (ii) no contraventions of APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)*.



Rod Shanley
Partner

Pitcher Partners
Sydney

23 February 2023

For personal use only

BCAL Diagnostics Limited
Condensed statement of profit or loss and other comprehensive income
For the half year ended 31 December 2022

	Notes	Half-year ended 31 December 2022 \$	Half-year ended 31 December 2021 \$
Revenue from continuing operations			
Income	3	1,007,638	409,334
Expenses			
Research and development		(2,345,341)	(960,001)
Personnel costs		(91,072)	(116,452)
Marketing		(53,485)	(72,346)
Consulting fees		(496,091)	(103,256)
Directors' fees		(104,239)	(75,344)
Regulatory expense		(70,153)	(246,521)
General and administration		(318,177)	(142,068)
Share based payments		-	(9,584)
Loss before income tax		(2,470,920)	(1,316,238)
Income tax		-	-
Net loss after tax		(2,470,920)	(1,316,238)
Other comprehensive income for the year		-	-
Total comprehensive loss for the year		(2,470,920)	(1,316,238)
Loss is attributable to:			
Members of BCAL Diagnostics Limited		(2,470,920)	(1,316,238)
Earnings per share			
<i>From continuing operations</i>		Cents	Cents
- Basic loss per share		(1.17)	(0.6)
- Diluted loss per share		(1.17)	(0.6)

The above Statement of Profit or Loss and Other Comprehensive Income should be read in conjunction with the accompanying notes.

BCAL Diagnostics Limited
Condensed statement of Financial Position
As at 31 December 2022

	Notes	31 December 2022 \$	30 June 2022 \$
ASSETS			
Current Assets			
Cash and cash equivalents		6,812,738	5,571,417
Tax receivables		828,158	780,223
Other receivables and prepayments		138,380	103,419
Other financial assets		-	4,000,000
Total Current Assets		7,779,276	10,455,059
Non-Current Assets			
Plant and equipment		156,173	135,204
Total Non-Current Assets		156,173	135,204
Total Assets		7,935,449	10,590,263
LIABILITIES			
Current Liabilities			
Trade and other payables		340,799	914,423
Provisions		66,000	36,000
Total Current Liabilities		406,799	950,423
Total Liabilities		406,799	950,423
Net Assets		7,528,650	9,639,840
EQUITY			
Contributed equity	5	19,231,951	18,871,951
Reserves		321,059	321,059
Accumulated losses		(12,024,360)	(9,553,170)
Equity		7,528,650	9,639,840

The above Statement of Financial Position should be read in conjunction with the accompanying notes.

BCAL Diagnostics Limited
Condensed Statement of Changes in Equity
For the half year ended 31 December 2022

	Contributed equity \$	Accumulated losses \$	Share based payment reserve \$	Total \$
2022				
At 1 July 2022	18,871,951	(9,553,170)	321,059	9,639,840
Total comprehensive Loss for the period	-	(2,470,920)	-	(2,470,920)
Share issue	360,000	-	-	360,000
At 31 December 2022	19,231,952	(12,024,090)	321,059	7,528,920

	Contributed equity \$	Accumulated losses \$	Share based payment reserve \$	Total \$
2021				
At 1 July 2021	9,456,232	(6,167,677)	318,300	3,606,855
Total comprehensive Loss for the period	-	(1,316,238)	-	(1,316,238)
Share issue	10,007,513	-	-	10,007,513
Cost of share issue	(621,793)	-	-	(621,793)
Share based payments	-	-	2,759	2,759
At 31 December 2021	18,841,952	(7,483,915)	321,059	11,679,096

The above Statement of Changes in Equity should be read in conjunction with the accompanying notes.

For personal use only

BCAL Diagnostics Limited
Condensed Statement of Cash Flows
For the half year ended 31 December 2022

	Note	Half-year ended 31 December 2022 \$	Half-year ended 31 December 2021 \$
Cash flows from operating activities			
Payments to suppliers and employees		(3,627,715)	(1,551,260)
Research and development tax offset received		875,527	289,142
Interest received		31,553	434
Net cash outflow from operating activities		(2,720,635)	(1,261,684)
Cash flow from investing activities			
Purchase of plant and equipment		(38,044)	(137,157)
Payments for other financial assets at amortised cost		-	(7,000,000)
Proceeds from term deposits		4,000,000	-
Net cash outflow from investing activities		3,961,956	(7,137,157)
Cash flows from financing activities			
Proceeds from share issue	5	-	10,000,688
Costs of share issue		-	(621,793)
Net cash inflow from financing activities		-	9,378,894
Net increase in cash and cash equivalents		1,241,321	980,053
Cash and cash equivalents at the beginning of the period		5,571,417	3,407,605
Cash and cash equivalents at end of the half year		6,812,738	4,387,658

The above Statement of Cash Flows should be read in conjunction with the accompanying notes.

BCAL Diagnostics Limited
Notes to the Financial Statements
For the half year ended 31 December 2022

1 Summary of significant accounting policies

(a) Basis of preparation

These condensed financial statements for the interim half year reporting period ended 31 December 2022 have been prepared in accordance with the requirements of the Corporations Act 2001 and Australian Accounting Standard AASB 134 *Interim Financial Reporting*, as appropriate for for-profit entities. Compliance with Australian Accounting Standards 134 ensures that the financial statements and notes comply with International Financial Reporting Standards IAS 34 'Interim Financial Reporting'.

The financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and the realisation of assets and discharge of liabilities in the normal course of business.

The interim financial report is intended to provide users with an update on the latest annual financial statements of the Company as at 31 December 2022. As such it does not include all the notes of the type normally included in an annual report. Accordingly, this report should be read in conjunction with the annual report for the year ended 30 June 2022 and any public announcements made during the interim reporting period.

The accounting policies and methods of computation have been consistently followed in this interim financial report as were applied in the previous annual financial statements for the year ended 30 June 2022.

Rounding of amounts

In accordance with ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191, the amounts in this report have been rounded to the nearest dollar unless otherwise stated.

(b) Going concern

The financial statements have been prepared on a going concern basis which contemplates the realisation of assets and the settlement of liabilities in the normal course of business.

As disclosed in the financial statements, the Company incurred losses of \$2,470,920, had net cash outflows from operating activities of \$2,720,635, net cash outflows from investing activities (other than term deposits) of \$38,044, for the half year ended 31 December 2022.

The Company had \$6,812,738 in cash on hand and term deposits at 31 December 2022.

The Directors have reviewed the cash flow forecast as at 31 December 2022 and are of the view that the Company has funding for its activities beyond the next twelve months as at that date. As a result, the Directors believe that the Company will be able to continue as a going concern and that it is appropriate to adopt the going concern basis in the preparation of the financial report. The financial report does not include any adjustments relating to the amounts or classifications of recorded assets and liabilities that might be necessary if the Company do not continue as a going concern.

(c) Critical accounting estimates and judgements

There have been no significant changes to the critical accounting estimates and judgements applied and disclosed in the 30 June 2022 annual report.

(d) New and revised accounting requirements applicable to the current half-year reporting period.

There are no new accounting standards or interpretations applicable that would have a material impact on the accounts of the Company.

BCAL Diagnostics Limited
Notes to the Financial Statements
For the half year ended 31 December 2022

2 Segment information

BCAL Diagnostics Limited is an Australian company developing a novel blood screening test to improve the early diagnosis and monitoring of breast cancer that is safe, cost effective, accurate and available to all women regardless of age, race and geographic location. Therefore, it only operates in one segment.

3 Other Income	Half year ended 31 December 2022	Half year ended 31 December 2021
	\$	\$
Research and development tax offset	785,366	408,900
Research and development tax offset, prior period adjustment	189,907	-
Interest received	32,365	434
	1,007,638	409,334

4 Other financial assets	31 December 2022	30 June 2022
	\$	\$
Term deposits	-	4,000,000

5 Contributed equity

(a) Share capital

	31 December 2022	31 December 2022	30 June 2022	30 June 2022
	No Shares	\$	No Shares	\$
Ordinary Shares Fully Paid	211,443,781	19,231,952	207,443,781	18,871,951

(b) Movements in ordinary share capital

	Date	Number of Shares	Issue price	\$
Closing balance 30 June 2021		160,000,002		9,456,232
Shares issued on ASX listing	21/7/2021	40,000,000	\$0.25	10,000,000
Advisor shares issued	21/7/2021	6,875,631	\$0.0001	688
Employee shares issued	29/12/2021	45,500	\$0.15	6,825
Cost of share issue		-		(621,793)
Closing balance 31 December 2021		206,921,133		18,841,952
Share issue on exercise of options	2/5/2022	522,648	\$0.574	30,000
Closing balance 30 June 2022		207,443,781		18,871,952
Issue of shares ¹	25/8/2022	4,000,000	\$0.09 ¹	360,000
Closing balance 31 December 2022		211,443,781		19,231,952

¹Issue of shares to Chief Executive Officer as part of remuneration, at a deemed price of \$0.09 per share. This amount accrued and expensed as a share based payment in June 2022.

BCAL Diagnostics Limited
Notes to the Financial Statements
For the half year ended 31 December 2022

(c) Options

As at the date of the financial statements, the following options over unissued ordinary shares were on issue:

Details	No of options¹	Issue date	Date of expiry	Conversion price (\$)
Employee options	3,467,353	20/11/2019	20/11/2024	\$0.0574
Employee options	1,788,912	30/01/2020	30/01/2025	\$0.0574
Director options	5,201,068	23/11/2020	23/11/2023	\$0.0574
Consultant options	577,896	23/11/2020	23/11/2023	\$0.0574
Total	<u>11,035,229</u>			

The vesting of options is subject to employee service periods. All of the options on issue have vested.

The Company recognised expenses of \$Nil in relation to share based payments for the half year (2021: \$9,584).

6 Commitments

There were no commitments as at 31 December 2022.

7 Contingencies

In the opinion of the directors, the Company did not have any contingent assets or liabilities at 31 December 2022.

8 Events subsequent to balance date

The Company has entered into a premises lease late in the financial year for a period of 5 years, with a rental, net of incentive at approximately \$200,000 per annum, net of GST. The rent commences on 1 April 2023.

As part of the capital equipment required for the laboratory the Company has purchased a Mass Spectrometer at a cost of \$950,370. The purchase is to be financed over 3 years, with a deposit of \$197,533 and a payment of \$24,739 per month over 36 months. All amounts are net of GST.

Other than as outlined above, there are no matters or circumstances that have arisen since the end of the financial period that have significantly affected or may significantly affect the operations of the Company, the results of those operations, or state of affairs of the Company in future financial years.

9 Dividends

There were no dividends paid, recommended or declared during the current or previous reporting period.

DIRECTORS' DECLARATION

The directors of the Company declare that:

1. In the directors opinion, the financial statements and notes thereto, as set out on pages 6 to 12, are in accordance with the Corporations Act 2001, including:
 - (a) complying with Australian Accounting Standard 134 *Interim Financial Reporting and the Corporations Regulations 2001*; and
 - (b) giving a true and fair view of the Company's financial position as at 31 December 2022 and performance for the half year ended on that date; and
2. In the directors' opinion there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.



Jayne Shaw
Executive Chair

23 February 2023

Pitcher Partners Sydney Partnership

Level 16, Tower 2 Darling Park
201 Sussex Street
Sydney NSW 2000

Postal Address
GPO Box 1615
Sydney NSW 2001

p. +61 2 9221 2099
e. sydneypartners@pitcher.com.au

**Independent Auditor's Review Report
To the Members of BCAL Diagnostics Limited
ABN 51 142 051 223**

Report of the Half-Year Financial Report**Conclusion**

We have reviewed the half-year financial report of BCAL Diagnostics Limited ("the Company") which comprises the condensed statement of financial position as at 31 December 2022, the condensed statement of profit or loss and other comprehensive income, condensed statement of changes in equity and condensed statement of cash flows for the half-year ended on that date, a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of the Company does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Company's financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Report* section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* ("the Code") that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001* which has been given to the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's review report.

Responsibility of the Directors for the Financial Report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility for the Review of the Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Company's financial position as at 31 December 2022 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit.



Rod Shanley
Partner



Pitcher Partners
Sydney

23 February 2023

For personal use only