

15 May 2023

# Lab opens revenue opportunity

## NEED TO KNOW

- New Sydney lab to expedite commercialisation
- Opens revenue opportunity
- To provide further data to support BCAL test

**Australian lab opened:** BCAL has opened its Sydney laboratory, a step to further develop its Liquid Chromatography Mass Spectrometry (LCMS) testing platform and its breast cancer screening test. BCAL's US commercialisation partner, Precion Inc, is finalising the test, with BCAL to establish and validate the workflows, test protocols and algorithms in the Sydney lab.

**Revenue opportunity:** The lab also opens the opportunity to generate revenues in advance of the BCAL test market entry, planned for 2024. The LCMS facility can be offered for both commercial tests and other research activities.

**Evidence to date supports high test accuracy:** Research studies to date of samples of ~1,200 patients have reported high accuracy with the BCAL test showing 91% sensitivity and 80% specificity.

## Investment Thesis

**Current SOC not ideal:** Mammography, the breast screening Standard of Care (SOC), is not ideal with high false test results leading to unnecessary intervention or delayed treatment. It is not very efficacious in younger age groups and dissuades many women as it is uncomfortable, intrusive and results in exposure to radiation. The Australian screening program sees a participation rate of ~55%.

**BCAL looks to answer the shortcomings:** BCAL's test is safe. As a blood test it offers wider availability and easily incorporated into the patient's routine GP based screening program. Confirmation of the accuracy that it has shown to date is expected to see significant uptake.

## Valuation

The current more risk-averse investment environment sees pre-revenue biotechs trading at significant discount to DCF valuations. MST's diluted DCF valuation of \$0.48ps compares a share price of \$0.09. MST looks to Inoviq (IIQ.AX -\$50m market cap) and Rhythm Biosciences (RHY.AX-\$90m market cap) to provide a guide. IIQ's two novel diagnostic programs in development /research stage. It reported FY22 sales revenue of \$275K from adjunct cytology test and research tool. RHY.AX, valued at of \$90m, is at market-entry stage, noting regulatory queries stalled its approval processes and discounted its market value. In MST's view, as the CY24 BCAL test launch approaches and LCMS revenues commence, the investor market will re-rate its R&D risk profile. Taking IIQ and RHY as current market guides, MST holds its valuation of ~\$60m /A\$0.21ps.

## Risks

MST's valuation assumptions carry risks/sensitivities including confirmation of the test, regulatory approval, market uptake, timing and funding. MST's assumptions may not be realised or vary from the estimates.

## Equities Research Australia

### Life Sciences & Plasma Products

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BCAL Diagnostics 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 12 years by independent groups based in the USA and Australia. BCAL's screening test aims to address many of the shortcomings of the current Standard of Care screening test, mammography.

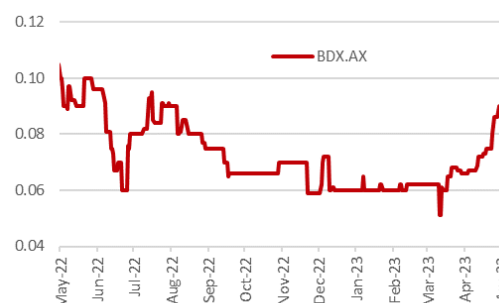
<https://www.bcaldiagnostics.com/>

Valuation	<b>A\$0.21ps</b> (unchanged)
Current price	<b>A\$0.09ps</b>
Market cap	<b>A\$19m</b>
Cash on hand	<b>A\$5.2m</b> (Mar Qtr)

## Potential Upcoming Catalysts and Newsflow

Period	
FY23	Confirmation of test assay/transfer Aust Lab
4QFY23	US Precion final analytical report
FY23	Seek LDT <sup>1</sup> approval in Aust
1QFY24	Clinical Decision Support Software analytics
CY24	First commercial sale of BCAL test

## Share Price Performance (A\$)



Source: FactSet, MST Access

<sup>1</sup> Laboratory Developed Test

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### Figure 1: Financial Summary

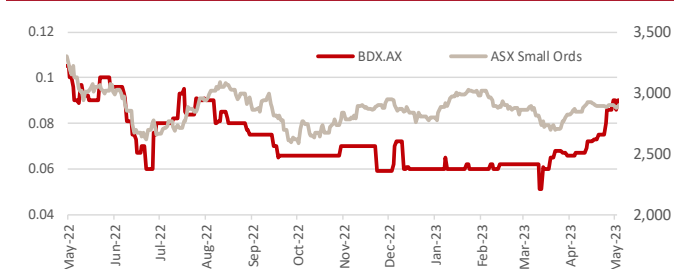
## BCAL Diagnostics Limited

Year end 30 June

## MARKET DATA

<b>Share Price</b>	<b>A\$</b>	<b>0.09</b>
52 week high / low	A\$	0.05 - 0.11
<b>Valuation (12 month forward)</b>	<b>A\$</b>	<b>0.21</b>
<b>Market capitalisation</b>	<b>A\$m</b>	<b>19.0</b>
Shares on issue	m	211
Options	m	12
Other equity	m	67
Potential shares on issue (diluted)	m	290

## 12 month performance



## INVESTMENT FUNDAMENTALS

EPS Reported (undiluted)	¢	(1.1)	(1.7)	(2.4)	(1.5)	0.7
<b>EPS Underlying (undiluted)</b>	<b>¢</b>	<b>(1.1)</b>	<b>(1.7)</b>	<b>(2.4)</b>	<b>(1.5)</b>	<b>0.7</b>
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
<b>P/E Reported (undiluted)</b>	<b>x</b>	<b>n/m</b>	<b>n/m</b>	<b>n/m</b>	<b>n/m</b>	<b>n/m</b>
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
<b>Dividend</b>	<b>¢</b>	-	-	-	-	-
Payout ratio	%	0%	0%	0%	0%	0%
<b>Yield</b>	<b>%</b>	-	-	-	-	-

**PROFIT AND LOSS (A\$)**

Revenue & Other Income	A\$m	0.3	0.7	1.0	2.5	9.5
Expenses	A\$m	(1.8)	(4.1)	(6.9)	(6.8)	(6.8)
<b>EBITDA</b>	<b>A\$m</b>	<b>(1.5)</b>	<b>(3.4)</b>	<b>(5.9)</b>	<b>(4.3)</b>	<b>2.7</b>
D&A	A\$m	-	(0.0)	(0.0)	(0.1)	(0.2)
<b>EBIT</b>	<b>A\$m</b>	<b>(1.5)</b>	<b>(3.4)</b>	<b>(5.9)</b>	<b>(4.4)</b>	<b>2.5</b>
Interest	A\$m	0.0	0.0	0.1	0.2	0.2
Tax	A\$m	-	-	-	-	(0.8)
<b>NPAT</b>	<b>A\$m</b>	<b>(1.5)</b>	<b>(3.4)</b>	<b>(5.8)</b>	<b>(4.1)</b>	<b>1.9</b>

**KEY RATIOS (A\$)**

KEY METRIC (%)		Y1E	Y2E	Y3E	Y4E	Y5E
Forecast year end shares	m	160	207	278	278	278
<b>Market cap (Y/E / Spot)</b>	<b>\$m</b>	<b>14.4</b>	<b>18.7</b>	<b>25.0</b>	<b>25.0</b>	<b>25.0</b>
Net debt /(cash)	\$m	(3.4)	(5.6)	(13.4)	(9.3)	(11.2)
<b>Enterprise value</b>	<b>\$m</b>	<b>11.0</b>	<b>13.1</b>	<b>11.6</b>	<b>15.7</b>	<b>13.9</b>
EV/Sales	x	40.0	18.7	11.9	6.3	1.5
<b>EV/EBITDA</b>	<b>x</b>	<b>(7.2)</b>	<b>(3.9)</b>	<b>(2.0)</b>	<b>(3.6)</b>	<b>5.2</b>
EV/EBIT	x	(7.2)	(3.8)	(2.0)	(3.6)	5.6
Net debt / Enterprise Value	x	(0.3)	(0.4)	(1.2)	(0.6)	(0.8)
<b>Gearing (net debt / EBITDA)</b>	<b>x</b>	<b>2.2</b>	<b>1.6</b>	<b>2.3</b>	<b>2.1</b>	<b>(4.2)</b>
Operating cash flow per share	\$	(0.0)	(0.0)	(0.0)	(0.0)	0.0
<b>Price to operating cash flow</b>	<b>x</b>	<b>(11.9)</b>	<b>(5.8)</b>	<b>(4.1)</b>	<b>(6.1)</b>	<b>12.1</b>
<b>Free cash flow</b>	<b>\$m</b>	<b>(1.2)</b>	<b>(7.2)</b>	<b>(2.2)</b>	<b>(4.1)</b>	<b>1.9</b>
Free cash flow per share	\$	(0.01)	(0.03)	(0.01)	(0.01)	0.01
<b>Price to free cash flow</b>	<b>x</b>	<b>(11.9)</b>	<b>(2.6)</b>	<b>(11.6)</b>	<b>(6.1)</b>	<b>13.3</b>
<b>Free cash flow yield</b>	<b>%</b>	<b>-8.4%</b>	<b>-38.8%</b>	<b>-8.6%</b>	<b>-16.5%</b>	<b>7.5%</b>
Book value / share	\$	0.02	0.05	0.05	0.04	0.04
<b>Price to book (NAV)</b>	<b>x</b>	<b>4.0</b>	<b>1.9</b>	<b>1.7</b>	<b>2.4</b>	<b>2.0</b>
NTA / share	\$	0.02	0.05	0.05	0.04	0.04
<b>Price to NTA</b>	<b>x</b>	<b>4.0</b>	<b>1.9</b>	<b>1.7</b>	<b>2.4</b>	<b>2.0</b>
EBITDA margin	%	n/m	n/m	n/m	n/m	28%
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	n/m	n/m	12.7

**BALANCE SHEET (A\$)**

BALANCE SHEET (A\$)		2017	2016	2015	2014	2013
Cash	A\$m	3.4	5.6	13.4	9.3	11.2
Receivables	A\$m	0.7	0.9	1.0	1.0	0.4
Inventory	A\$m	-	-	-	0.1	0.2
PPE	A\$m	0.0	0.1	0.2	0.2	0.2
Intangibles	A\$m	-	-	-	-	-
Other	A\$m	-	4.0	0.8	0.8	0.8
<b>Total Assets</b>	<b>A\$m</b>	<b>4.1</b>	<b>10.6</b>	<b>15.4</b>	<b>11.4</b>	<b>12.8</b>
Payables	A\$m	0.5	0.9	1.0	1.0	0.4
Borrowings	A\$m	-	-	-	-	-
Leases	A\$m	-	-	-	-	-
Provisions	A\$m	0.0	0.0	0.1	0.1	0.1
Other	A\$m	-	-	-	-	-
<b>Total Liabilities</b>	<b>A\$m</b>	<b>0.5</b>	<b>1.0</b>	<b>1.1</b>	<b>1.1</b>	<b>0.5</b>
<b>Shareholder's Equity</b>	<b>A\$m</b>	<b>3.6</b>	<b>9.6</b>	<b>14.4</b>	<b>10.3</b>	<b>12.3</b>

## CASH FLOW (A\$)

Receipts from customers	A\$m	-	-	-	0.2	7.2
Payments to suppliers and employees	A\$m	(1.6)	(3.5)	(4.4)	(1.5)	(1.5)
R&D	A\$m	-	-	(2.7)	(5.3)	(5.3)
Govt Grants, Rebates & Milestones	A\$m	0.4	0.3	0.9	2.3	2.3
Interest	A\$m	0.0	0.0	0.1	0.2	0.2
Tax	A\$m	-	-	-	-	(0.8)
<b>Operating cash flow</b>	<b>A\$m</b>	<b>(1.2)</b>	<b>(3.2)</b>	<b>(6.1)</b>	<b>(4.1)</b>	<b>2.1</b>
Capex	A\$m	(0.0)	(0.0)	(0.1)	(0.1)	(0.2)
Acquisitions	A\$m	-	-	-	-	-
Other	A\$m	-	(4.0)	4.0	-	-
<b>Investing cash flow</b>	<b>A\$m</b>	<b>(0.0)</b>	<b>(4.0)</b>	<b>3.9</b>	<b>(0.1)</b>	<b>(0.2)</b>
Borrowings	A\$m	-	-	-	-	-
Equity	A\$m	4.2	9.4	10.0	-	-
Dividend	A\$m	-	-	-	-	-
<b>Financing cash flow</b>	<b>A\$m</b>	<b>4.2</b>	<b>9.4</b>	<b>10.0</b>	<b>-</b>	<b>-</b>
Change in Cash / FX	A\$m	3.0	2.2	7.8	(4.1)	1.9
<b>Year end cash</b>	<b>A\$m</b>	<b>3.4</b>	<b>5.6</b>	<b>13.4</b>	<b>9.3</b>	<b>11.2</b>

Source: MST, Company Reports

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## Opening of in-house 'lab' brings advantages

Following the November 2022 announcement of its plan to establish a commercial pathology laboratory in Sydney, BCAL has announced that the laboratory has been commissioned. The lab's Liquid Chromatography Mass Spectrometry (LCMS) platform technology will be used for both the ongoing development of BCAL's breast cancer screening test and commercial pathology testing/R&D services. Its US commercialisation partner, Precion Inc. is advancing the development of the BCAL test, with the Sydney lab to establish and validate the workflows, test protocols and algorithms.

The inhouse laboratory with an LCMS offers a number of advantages:

- Control the ability to expedite BCAL tests development program and its marketing of the test once approved.
- Early revenue generation.
- Build awareness of the test in public and medical domains.
- Gain additional samples to further confirm the test's accuracy.

With the establishment of the laboratory and confirmation of the test, BCAL plans to seek approval of the test under Australian and the US Laboratory Developed Test (LDT) protocols. LDTs are developed for use in one pathology centre/network. BCAL plans to initially offer the test as a complement to the current imaging technologies, such as mammograms. The longer-term aim is to further develop the test to offer monitoring and screening for women of all ages and backgrounds in any location. Revenues are expected from CY24.

## Investment Thesis

BCAL has developed a novel technology to detect breast cancer. Early cancer diagnosis commonly carries significantly higher survival rates. While the benefits of screening have seen government and/or healthcare payer funded screening programs introduced in a number of countries, many women do not take advantage of the programs.

### Challenges with mammography

The current standard of care (SOC), mammography, is not ideal as:

- **Level of test accuracy:** False positive and false negative test results can lead to unnecessary intervention or delayed treatment.
- **Lower efficacy in younger age groups:** Mammograms are generally not as effective in younger women.
- **Radiation exposure:** Mammography's X-ray based technology presents a safety risk.
- **The discomfort and intrusive nature of the testing protocol:** Eligible women are deterred because of the associated pain and/or cultural/religious reasons.

### BCAL's blood test to answer the problem

BCAL's blood test screening technology presents opportunity through:

- **The need is significant:** Breast cancer is the most common cancer in the US, excluding skin cancers. Screening programs to enable early diagnosis draw strong support from numerous countries' health and regulatory bodies. Existing screening programs may present ready access to large markets for BCAL. Noting BCAL initially plans to market the test to be used in conjunction with existing tests such as a mammogram.
- **Convenience with the blood test to be easily incorporated into existing routine medical visits.** As a blood test, the BCAL test aims to be incorporated into doctor visits for other screening program tests – for example, for cholesterol, bone density, or cervical smears. In MST's view, the convenience and ease of a blood test is likely to see participation rates increase.

# Valuation, Risks Sensitivities

## Valuation

The current more risk-averse investment environment sees pre-revenue biotechs trading at significant discount to DCF valuations. MST's diluted DCF valuation of \$0.48ps compares a share price of \$0.09. MST looks to Inoviq (IIQ.AX- \$50m market cap) and Rhythm Biosciences (RHY.AX-\$90m market cap) to provide current market-based valuations. IIQ's two novel diagnostic programs in development /research stage. It reported FY22 sales revenue of \$275K from adjunct cytology test and research tool. RHY.AX is at market-entry stage, noting regulatory queries have stalled its approval processes and discounted its market value. In MST's view, as BCAL's test launch approaches and LCMS revenues commence over CY24, the investor market will re-rate its R&D risk profile. Taking IIQ and RHY as current market guides, MST holds BCAL at ~\$60m /A\$0.21ps.

## Risks

The valuation is subject to the usual risks and sensitivities, both upside and downside, of biotechnology development. BCAL is yet to finalise its test and receive approval. The timing may vary from the model's assumptions. In addition, costs may exceed MST's expectations resulting in the need for earlier funding. The company has announced it will pursue a LDT pathway to market. While offering a faster route, revenues are commonly limited in comparison to the FDA/TGA/EMA<sup>2</sup> regulatory authorities with limited reimbursement. The company may decide to undertake the traditional regulatory approval route with longer timelines to market entry.

From a revenue perspective, the price and reimbursement for the test are yet to be established. MST notes that pricing is likely to vary in the different markets. The need for effective breast screening sees intense interest bringing potential competition. Other tests may be approved.

From an intellectual property perspective, BCAL's License Agreement with the University Louisville Research Foundation (ULRF) includes a provision that BCAL must use reasonable efforts to achieve the commercial goals and have relevant products ready for commercial sale by 31 July 2023, unless otherwise extended. BCAL has updated its agreement with ULRF to accommodate the projected launch date. MST's valuation carries the usual industry risks/sensitivities which include confirmation of the test, regulatory approval, market uptake, price of the test, timing and funding. MST's assumptions may not be realised or vary in timing and size.

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<sup>2</sup>TGA = Therapeutics Goods Administration Authority  
FDA = Food Drug Administration  
EMA = European Medicines Agency

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