BCAL Diagnostics

BDX.AX

MST Access
A research platform of MST Financial

14 August 2024

Preparing for Test Launch

NEED TO KNOW

- **US health agencies endorse earlier screening**
- **BDX continues on track to market launch in late CY24**
- **BDX's blood test to address current challenges**

USPSTF[1] screening endorsement: The decision to expand recommendation for US breast cancer screening looks to increase BDX's potential market.

On track for end CY24 launch: BDX plans to launch its novel test in Australia by end CY24. It will be used initially in conjunction with mammography.

Blood test to answer current deterrents: As a blood test, BDX aims to address many of the current challenges of breast screening programs, particularly participation rates.

Investment Thesis

Expanding markets: The breast cancer screening market continues to grow. The USPSTF has joined other agencies, with the recommendation to lower the starting age for breast screening from 50 years to 40 years in the US.

Current Standard of Care (SOC) is not ideal: Low participation rates are attributed to radiation exposure and discomfort associated with current standard of care, mammography. It is also not very efficacious in the denser breast tissue of younger women.

BDX looks to answer the shortcomings: BDX's test is safe. As a blood test it offers wider availability and could be easily incorporated into the patient's routine general practitioner (GP) based screening program. Confirmation of the accuracy of results that have been demonstrated to date, is expected to see significant uptake. BDX's continued refinement of the test strengthens its commercial thesis from a cost and consumer access perspective.

Valuation, Risks & Sensitives

The current, more risk-averse investment environment sees pre-revenue biotechs trading at significant discount to DCF valuations. MST looks to Inoviq (IIQ.AX A$54m) and Cleo Diagnostics (COV.AX A$24m) as market-based comparators. In MST's view, BDX offers a clear route to market at end CY24, was well ahead of the comparable companies. MST believes investors will re rate the stock as BDX progresses to planned product launch in late CY24. MST's valuation of A$74m ($0.20cps up from $0.18cps), carries the usual industry risks/sensitivities which include confirmation of the test, regulatory approval, market uptake, price of the test, timing, funding and competition. MST's assumptions may not be realised or vary in timing and size.

Equity Research Australia

Pharmaceuticals, Biotechnology/Life Sciences

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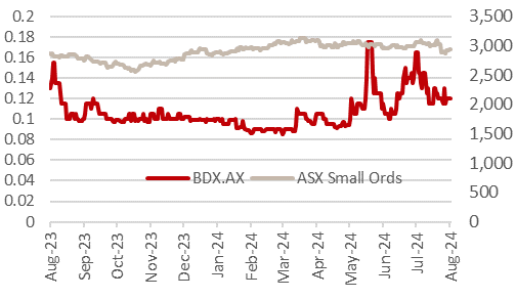
BCAL Diagnostics is developing a non-invasive laboratory blood test for the detection of breast cancer. The core BDX technology has evolved from extensive research and investment over approximately 12 years by independent groups based in the USA and Australia. BDX's screening test aims to address many of the shortcomings of the current Standard of Care screening test, mammography. www.bcaldiagnostics.com

Valuation	**A$0.20** *(from A$0.18)*
Current price	**A$0.12**
Market cap	**A$41.1m**
Cash on hand	**A$6.2m** *(MSTe 30 Jun 24)*

Additional Resources

Sept 24	Certification LDT Aus Laboratory
H2FY24	US tech transfer to Aus Lab
Late CY24	Launch BDX test in Australia

Share Price (A$)



Source: FactSet, MST Access

[1] USPSTF - US Preventative Services Task Force

Figure 1: Financial Summary

BCAL Diagnostics Limited — BDX-AU

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.12**
52 week high / low	A$	0.185-0.085
Valuation (12 month forward)	**A$**	**0.20**
Market capitalisation	**A$m**	**41.1**
Shares on issue	m	357
Options	m	11
Other equity	m	-
Potential shares on issue (diluted)	m	368

12 month performance

INVESTMENT FUNDAMENTALS		FY22A	FY23A	FY24E	FY25E	FY26E
EPS Reported (undiluted)	¢	(1.7)	(2.4)	(1.6)	(1.9)	1.1
EPS Underlying (undiluted)	**¢**	**(1.7)**	**(2.4)**	**(1.6)**	**(1.9)**	**1.1**
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**	**-**

PROFIT AND LOSS (A$)		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue & Other Income	A$m	0.7	2.8	3.1	2.5	12.4
Expenses	A$m	(4.1)	(7.8)	(7.4)	(9.3)	(6.8)
EBITDA	**A$m**	**(3.4)**	**(5.0)**	**(4.2)**	**(6.8)**	**5.6**
D&A	A$m	(0.0)	(0.1)	(0.3)	(0.1)	(0.2)
EBIT	**A$m**	**(3.4)**	**(5.1)**	**(4.5)**	**(6.9)**	**5.3**
Interest	A$m	0.0	0.0	(0.0)	0.1	0.1
Tax	A$m	-	-	-	-	(1.6)
NPAT	**A$m**	**(3.4)**	**(5.1)**	**(4.5)**	**(6.7)**	**3.8**

KEY RATIOS (A$)		FY22A	FY23A	FY24E	FY25E	FY26E
Forecast year end shares	m	207	212	314	357	357
Market cap (Y/E / Spot)	**$m**	**16.6**	**24.4**	**36.1**	**41.1**	**41.1**
Net debt /(cash)	$m	(9.6)	(3.2)	(6.2)	(3.4)	(7.1)
Enterprise value	**$m**	**7.0**	**21.2**	**29.9**	**37.7**	**34.0**
EV/Sales	x	10.0	7.6	9.6	15.1	2.7
EV/EBITDA	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**6.1**
EV/EBIT	x	n/m	n/m	n/m	n/m	6.4
Net debt / Enterprise Value	x	n/m	n/m	n/m	n/m	n/m
Gearing (net debt / EBITDA)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	(0.0)	0.0
Price to operating cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**10.2**
Free cash flow	**$m**	**(3.2)**	**(6.4)**	**(6.1)**	**(6.7)**	**3.8**
Free cash flow per share	$	(0.02)	(0.03)	(0.02)	(0.02)	0.01
Price to free cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**10.9**
Free cash flow yield	**%**	**-13.6%**	**-26.4%**	**-16.9%**	**-16.4%**	**9.2%**
Book value / share	$	0.05	0.02	0.02	0.01	0.03
Price to book (NAV)	**x**	**2.5**	**4.7**	**4.6**	**8.2**	**4.6**
NTA / share	$	0.05	0.02	0.02	0.01	0.03
Price to NTA	**x**	**2.5**	**4.7**	**4.6**	**8.2**	**4.6**
EBITDA margin	%	n/m	n/m	n/m	n/m	45%
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	n/m

BALANCE SHEET (A$)		FY22A	FY23A	FY24E	FY25E	FY26E
Cash	A$m	9.6	3.2	6.5	3.6	7.4
Receivables	A$m	0.9	3.0	1.0	1.0	1.0
Inventory	A$m	-	-	0.1	0.1	0.3
PPE	A$m	0.1	1.1	1.7	1.7	1.7
Intangibles	A$m	-	-	-	-	-
Other	A$m	-	1.0	0.9	0.9	0.9
Total Assets	**A$m**	**10.6**	**8.4**	**10.2**	**7.3**	**11.3**
Payables	A$m	0.9	2.0	1.0	1.0	1.0
Borrowings	A$m	-	-	0.3	0.3	0.3
Leases	A$m	-	1.1	1.0	1.0	1.0
Provisions	A$m	0.0	0.1	0.1	0.1	0.1
Other	A$m	-	-	-	-	-
Total Liabilities	**A$m**	**1.0**	**3.2**	**2.3**	**2.3**	**2.3**
Shareholder's Equity	**A$m**	**9.6**	**5.2**	**7.8**	**5.0**	**9.0**

CASH FLOW (A$)		FY22A	FY23A	FY24E	FY25E	FY26E
Receipts from customers	A$m	-	-	-	0.2	10.1
Payments to suppliers and employees	A$m	(1.4)	(1.1)	(1.9)	(4.0)	(1.5)
R&D	A$m	(2.1)	(6.0)	(6.6)	(5.3)	(5.3)
Govt Grants, Rebates & Milestones	A$m	0.3	1.0	3.0	2.3	2.3
Interest	A$m	0.0	0.0	0.0	0.1	0.1
Tax	A$m	-	-	-	-	(1.6)
Operating cash flow	**A$m**	**(3.2)**	**(6.1)**	**(5.4)**	**(6.7)**	**4.0**
Capex	A$m	(0.0)	(0.4)	(0.7)	(0.1)	(0.2)
Acquisitions	A$m	-	-	-	-	-
Other	A$m	-	-	-	-	-
Investing cash flow	**A$m**	**(0.0)**	**(0.4)**	**(0.7)**	**(0.1)**	**(0.2)**
Borrowings	A$m	-	-	(0.4)	-	-
Equity	A$m	9.4	0.1	9.9	3.9	-
Dividend	A$m	-	-	-	-	-
Financing cash flow	**A$m**	**9.4**	**0.1**	**9.4**	**3.9**	**-**
Change in Cash / FX	A$m	6.2	(6.4)	3.3	(2.8)	3.8
Year end cash	**A$m**	**9.6**	**3.2**	**6.5**	**3.6**	**7.4**

Comparable Companies

Company	**Inoviq Ltd (IIQ.AX)**	**Company**	**Cleo Diagnostics**
Description	Portfolio of on market and in-development tests	**Description**	Early stage ovarian cancer blood test
Market Cap	A$54m	**Market Cap**	A$24m

Source: MST Access, Company Reports

+ve screening changes support BDX launch

BDX's planned market launch for end CY24 looks to be well timed with the market dynamics looking increasingly positive. The consensus for earlier breast screening is strengthening. A key US advisory authority, US Preventive Services Task Force (USPSTF), has recommended that women from the age of 40 years should commence mammography screening for breast cancer. The USPSTF recommends biennial screening mammography for women aged 40 to 74 years. Its decision joins the earlier recommendation of the American Cancer Society, for women to have the option to commence annual mammograms from 40-45 years and women 45 to 54 should have mammograms every year.

Increasing incidence in younger cohorts

Breast cancer is the second most common cancer and the second most common cause of cancer death for women in the United States. Mammography, X rays of the breast tissue, is the standard of care (SOC) screening modality. The benefits and risks of breast cancer screening differ by age;

- Older women have a higher rate of breast cancer which has supported the 'risk' of X ray technology of mammography. Their less dense breast tissue is also more amenable to the X ray technology.
- To date, mammography screening programs for younger women generally have not been considered effective – noting some exceptions. While breast cancer in younger women tends to be more aggressive, the lower incidence has not supported the overall return on a screening program. Safety is another factor. Exposure to the X-ray based screening over a longer time brings higher radiation risk. From an efficacy perspective there are also challenges - mammography is less effective in younger women as the denser breast tissue of these women commonly leads to false positive results. Follow up biopsies can lead to unnecessary anxiety for the 'patient' and cost.

However, the risk / reward perspective is changing. A rising incidence rate and more aggressive pathology in 40-49 year old women see an unmet need for an effective safe screening methodology for this cohort. The latest data, which span 2015 to 2019, show a 2% increase in breast cancer diagnoses per year among women in their 40s (See MST report 11 Oct 23 Funding for Test Development).

Medical authorities respond – expanding screening recommendation

The USPSTF has acknowledged the change in risk for younger women. It now recommends that all women to be screened every other year starting at age 40 years. Previously the USPSTF recommended that women in their 40s make an individual decision about when to start screening based on their health history and preferences. The USPSTF classifies the decision as 'B grade' the second highest of five categories. B grade indicates that more research is needed to determine whether and how additional screening might help women with dense breasts stay healthy.

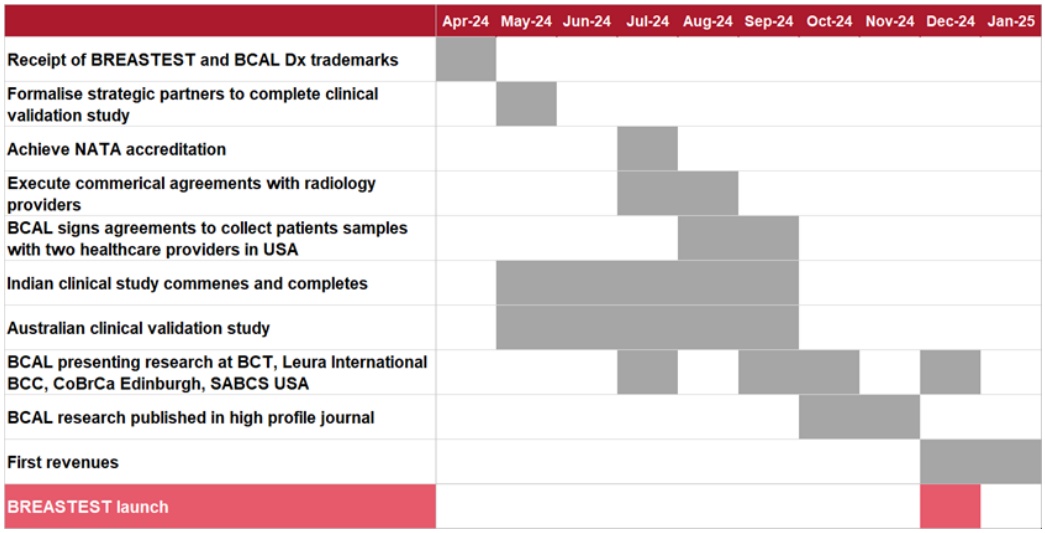
Other countries to follow?

Australia already includes 40 year olds in its biennial program. The EU recommendation for screening generally includes all women aged 45 to 74 years. For those aged 50 to 69 screening is recommended every 2 years; for age 45 to 49 years, every 2 to 3 years; for age 70 to 74, every 3 years. To date, the European countries' guidelines are unchanged. The UK program commences at 50 years old.

This news flow looks to expand BDX's potential market as it approaches market launch.

Steps to CY 24 launch

Figure 2: Steps to a BREASTest Launch



Source: BDX

BDX has developed an indepth program to market launch;

- BDX's Sydney laboratory will serve as its Australian Laboratory Developed Test (LDT) lab. It will provide testing facilities for clinical validation studies and establish quality systems and protocols to comply with regulatory standards. An informal visit from National Association of Testing Authorities (NATA) has provided guidance around the procedures, protocols and quality of NATA systems required to meet its standards.
- Mr Shane Ryan, with 20 years experience in the global oncology market, has been appointed as Chief Executive Officer (CEO). Previous roles include Global Senior Vice President Strategy and Innovation – Patient Access at Genesis Care.
- BREASTEST™ will be initially offered in conjunction with Standard of Care (SOC) mammography. Clinical data will be collected for comparison to mammography and better understand BREASTEST's role in the screening programs.
- Over Q3CY24, marketing activities will include the establishment of a national network of domestic and global Key Opinion Leaders (KOL) to facilitate the Australian market uptake of the test and international awareness. Awareness of the test will be highlighted with KOLs through 1:1 meetings, conferences and educational webinars. Breast surgeons, breast clinics, GPs, radiology and pathology providers as well as advocacy groups and government will also be targeted.
- Initial targets will be NSW and Victoria. The company intends to convert its existing sample collection sites into commercial partners. The test will initially be offered as an In Vitro Diagnostic Test (IVD). While the pathway restricts the use of the test to the nominated laboratory or laboratory network, it presents advantages including lower cost and a streamlined approval process allowing for expedited market entry.

The initial implementation program will be patient funded testing as BDX accumulates the data to support government / health payers support.

- Data from the testing will help to 'fine' tune the testing procedures. Over time, as demand grows for wider use across multiple pathology laboratories, BDX may seek approval by the FDA, TGA and other domains' regulatory bodies to establish inclusion in the appropriate therapeutic registers, enabling wider market access.

Initiatives to raise awareness in the other Australian states will also be undertaken, in preparation for later market launches. Expansion of the sale of the test into other Australian states and territories is planned with the US to follow in CY25. BCAL has commenced building the essential clinical partnerships and sample collection necessary for clinical verification & validation in the USA market.

- From an IP perspective, BDX continues to build its position with further patent filings. The first provisional application, submitted in May 2022 has entered the Patent Cooperation Treaty (PCT - full patent) phase.

Key commercialisation Activities:

- Clinical laboratory expansion: BDX's capital investment in its state-of-the-art clinical laboratory and patient sample processing facility, will assist with automation and the installation of three commercial grade mass spectrometers. The investment lifts the commercial capacity to more than 100,000 tests per annum.
- Preparations for accreditation of the laboratory's quality systems and documentation required for assessment of the laboratory by NATA are nearing completion.
- BCAL continues to seek trademark protection for the BREASTEST® name. Registration in Australia is complete. BCAL Dx mark was registered in the UK. Other likely markets include USA, EU, UK, Canada, China, India, South Korea and New Zealand.
- Other activities: In Australia, BCAL's National Key Opinion Leader network has continued to provide clinical guidance and support to the company's clinical study and market entry activities. In the US, first patients were recruited in June in the study to provide data for the market entry in the USA.

Figure 3: Commercialisation program

2024	2025	2026
Launch BREASTEST in Australia late CY24	Nationwide market access initiatives	Scientific literature on BCAL performance
Initial focus NSW & Vic	Define/ initiate US strategy	Aus Government funding for BCAL test
Awareness program for all stakeholders	Define US market launch strategy	Prepare for US launch
Seek strategic partners	Expand Sydney lab processing capability	Expand cancer product portfolio
Software/Algorith development/validation		Grow Australian volume
BREASTEST™ analytical performance		
BREASTEST™ analytical verification		
BREASTEST™ analytical validation		
Clinical Lab accreditation		
LIMS set up and implementation		
NATA (ISO 15189) Technical File		
NATA Audit		
BREASTEST™ Clinical validation		
BREASTEST™ Launch		

Source: BDX

Valuation, Risks, Sensitivities

Investment case

News flow strengthens MST's investment case: the expansion of the recommended breast screening ages is expected to increase BDX's potential market.

MST's investment case has been built on:

1. **Large potential markets:** 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 BDX.
2. **Compatibility with existing routine medical practices:** As a blood test, over time, the BDX test may be incorporated into doctor visits for other screening program tests – for example, testing for cholesterol and cervical smears. In MST's view, the convenience and ease of a blood test is likely to see participation rates increase.
3. **Answering the challenges of mammography:**

- **Level of test accuracy:** The challenges of mammography screening as well as the subjectivity of interpretation of the results pose challenges. As discussed, false positive/negative test results can lead to unnecessary intervention or delayed treatment. While still to be confirmed, BDX's testing to date supports high specificity and sensitivity.
- **Lower efficacy in younger age groups:** Mammograms are generally less 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:** Many eligible women are deterred because of the associated pain and/or cultural/religious reasons.

Valuation

BDX remains on track for its planned market launch, a key valuation step, at end CY24. As a screening test, it promises large markets. In addition to Australia, it is targeting the world's largest market, the US. MST's valuation of A$74m (previously A$60m) is based on comparative valuation to Cleo Diagnostics (COV.AX) and Inoviq (IIQ-AX). COV's A$43m valuation presents as an earlier stage asset with smaller initial market. While IIQ's pipeline offers a wider range of tests, the majority of key assets are also generally in early stage and targeting smaller markets as monitoring tools. All companies reported similar cash (~A$9-10m) at June 30, 2024.

Cleo Dx (COV.AX) – Market Cap A$42m

COV is developing blood tests for the detection of ovarian cancer, with its triage kit reporting 95% sensitivity and 95% specificity in distinguishing cancerous samples from healthy ones. It is targeting a 2025 US release of its first product, a pre-surgical triage test called AdnexaSure. US trials for this product have begun, and Australian trials have received approval.

The company is planning two additional ovarian cancer testing products: a post-surgical recurrence test for previously treated patients and an ovarian screening test, which could potentially target a much larger market as a screening product. However, no release timeline has been announced for these two products.

Cash at the bank as of 30 June 2024 was A$9.4 million.

Inoviq (IIQ.AX) – Market cap – A$62.3m

IIQ offers a larger pipeline, including research tools, diagnostics, and a therapeutic, with two products currently on the market. These products are a diagnostic research tool and an adjunct for cytology in bladder screening, with revenues for H1FY24 reported as A$288K.

IIQ's product pipeline is predominantly in the early stages, exploring breast and ovarian cancer diagnostics. Its most advanced product, neuCA15-3, due for release in 2025, is intended for monitoring breast cancer patients, offering a smaller potential cohort compared to screening. Other screening diagnostics and therapeutics are in earlier stage development. While IIQ already has revenue flow significant revenue upside is still to be realised.

Cash at the bank as of 30 June 2024 was A9.2 million.

Risks Sensitivities

The valuation is subject to the usual risks and sensitivities, both upside and downside, of biotechnology development. BDX is yet to finalise its test and receive approval. The timing may vary from the model's assumptions or the test may not receive approval in the key markets. Full details commercialisation plans. The company may decide to undertake the more formal processes, potentially resulting in longer timelines to market entry. The need for effective breast screening sees intense interest. Other tests may be approved, bringing potential competition. The clinical need may also bring potential acquirors/ licensing partners.

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. Pricing may vary from our assumptions. From an intellectual property perspective, BDX has a License Agreement with the University of Louisville Research Foundation (ULRF) that cover the use of certain lipids in the diagnosis of breast and lung cancer. BDX has updated its agreement with URLF to accommodate the projected launch date. Patents have been issued in Australia, Japan, Hong Kong, Europe, with patents in final stages in US and Canada. BDX has filed two patent applications of its own.

Company disclosures

The companies and securities mentioned in this report, include:

BCAL Diagnostics (BDX.AX) | Price A$0.12 | Valuation A$0.20;

Price and valuation as at 14 August 2024 (not covered)*

Additional disclosures

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