

COMPANY PROFILE

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian-based biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. BARD1's proprietary technology platform is based on novel tumour markers with potential diagnostic and therapeutic applications across multiple cancers. The pipeline includes two development-stage BARD1 autoantibody tests for early detection of lung and ovarian cancers, and a research-stage cancer vaccine under evaluation for treatment of cancer. Additional diagnostic projects are being evaluated for prostate, breast and other cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients' lives. BARD1 is headquartered in Perth, Australia, and has contract research laboratories at University of Geneva, Switzerland.

HIGHLIGHTS

- **Biotech company** focused on developing non-invasive diagnostics for early detection of cancer to save patients' lives
- **Platform technology** of BARD1 tumour markers with potential diagnostic and therapeutic applications across multiple cancers
- **Diagnostic tests** in development for lung and ovarian cancers
- **Cancer vaccine** project at research-stage
- **Pilot studies** demonstrating accuracy of BARD1 autoantibody panels for detection of lung and ovarian cancers with high sensitivity and specificity
- **Planned studies** to further develop and validate the performance of BARD1 tests
- **Large market opportunities** and diversified risk across 3 programs

CORPORATE INFORMATION

Listed	20 June 2016
Industry	Biotechnology
Products	Cancer diagnostics
Headquarters	Perth, Australia
Employees	<5 FTE
Ticker	ASX:BD1
Ordinary Shares	742M
Market Cap @13/3/18	A\$19.29m
Share Price @13/3/18	A\$0.026
52w H/L Range	A\$0.064-0.006
Cash @31/12/17	A\$1.2m

ASX:BD1 SHARE PRICE CHART



BUSINESS MODEL

BARD1 plans to develop a portfolio of non-invasive diagnostic tests for early detection, diagnosis or monitoring of cancer, conduct clinical validation studies to demonstrate the performance of its BARD1 Tests and enable medical device marketing, and then commercialise its products through licensing its diagnostic tests to clinical laboratory, major diagnostic or biopharmaceutical partners in the USA, Europe and Asia for upfront fees, milestone payments, and royalties on sales. Importantly, BARD1 will strive to create value for ASX:BD1 shareholders.

MARKET OPPORTUNITIES

The **global cancer diagnostics market** was valued at US\$100.9B in 2013 (TMR 2014). BARD1 diagnostics are targeting the US\$26.0B lung cancer and US\$7.2B ovarian cancer segments that have an unmet clinical need for non-invasive, accurate and affordable diagnostic tests for early detection of cancer.

Global Cancer Diagnostics Market (USD million)

Application	2013	% share
Lung Cancer	\$ 26,043.90	25.8%
Ovarian Cancer	\$ 7,246.40	7.2%
TOTAL	\$ 100,994.40	100.0%

Source: Transparency Market Research 2014

Additionally, the **global cancer vaccine market** was valued at US\$3.5B in 2016 (BCC 2016). BARD1 therapeutics have the potential to provide safe, effective and targeted solutions for the prevention and/or treatment of multiple cancers.

TECHNOLOGY

The proprietary BARD1 Technology includes BARD1 tumour markers, diagnostic assays and algorithms. BARD1 tumour markers have potential utility as **diagnostic biomarkers** for the detection and monitoring of cancer, and **therapeutic targets** for immunotherapies used in the treatment of cancer. The technology has potential applications across lung, breast, ovarian, prostate, colorectal and other cancers.

Normal cells express BARD1 protein that plays an important role in cell growth regulation, DNA repair, and tumour suppression. Cancer cells express abnormal BARD1 proteins that drive oncogenesis and are correlated with cancer progression and poor prognosis. Abnormal BARD1 proteins are immunogenic and induce BARD1 autoantibodies that can be detected in the blood of people with cancer across early to late stages.

PRODUCTS & PIPELINE

BARD1 is building a portfolio of BARD1 Tests for the screening, diagnosis and monitoring of cancer to help save people's lives. BARD1 currently has two BARD1 autoantibody tests in development for early detection of lung and ovarian cancers. BARD1 autoantibody tests measure multiple BARD1 autoantibodies in the blood and use a proprietary algorithm to combine these levels into a cancer score that identifies the presence or absence of a specific cancer.

PRODUCT	INDICATION	PLATFORM	USE	RESEARCH	ASSAY DEVELOPMENT	CLINICAL VALIDATION	MARKETING / APPROVAL
BARD1 Lung	Lung Cancer	ELISA (Blood)	Screening & Risk Assessment	→			
BARD1 Ovarian	Ovarian Cancer	ELISA (Blood)	Detection & Monitoring	→			

- **BARD1-Lung:** ELISA-based blood test in development for screening and risk-assessment of lung cancer
- **BARD1-Ovarian:** ELISA-based blood test in development for detection and monitoring of ovarian cancer
- **BARD1-Vaccine:** research-stage cancer vaccine under evaluation for treatment of cancer

POTENTIAL BENEFITS OF BARD1 TESTS

Most lung and ovarian cancers are diagnosed at a late stage after symptoms have appeared, resulting in a poor prognosis with low overall 5-year survival rates of 18% and 46% respectively. Earlier detection by finding cancer when local rather than distant may increase 5-year survival from 4% to 55% for lung cancer, and 29% to 92% for ovarian cancer, a potential survival improvement of 13x and 3x respectively.

BARD1 Tests may address unmet needs for early detection of cancer in high-risk asymptomatic people to help inform decision-making and save people's lives. Potential benefits include:

Non-invasive	Safe and convenient blood sample
Sensitive	Accurately detects people with cancer
Specific	Avoids unnecessary invasive and costly follow-up procedures
Cost-effective	Affordable and reduces healthcare costs
Early detection	Enables earlier treatment, improves patient outcomes and saves lives

A positive test result may suggest that a patient should be referred for more invasive and costly imaging, biopsy or surgical procedures, whereas a negative test result may suggest that a high-risk patient should have an annual BARD1 Test.

VALIDATION RESULTS

BARD1's R&D activities are primarily focused on the clinical translation of BARD1 biomarkers into accurate and reliable diagnostic tests for unmet needs in cancer. Studies are underway to research, develop and validate BARD1 Tests for early detection of cancer.

Pilot studies have been completed to evaluate and optimise BARD1 multianalyte panels and algorithms for detection of lung, ovarian and other cancers. These retrospective, case-control studies in cancer patients and healthy controls showed the accuracy of research BARD1 panels at discriminating people with and without cancer, and the potential of developing commercial BARD1 Tests with high sensitivity and specificity for early detection of lung and ovarian cancers.

Product	Study	n	Model AUC	Test AUC	Sens	Spec
BARD1 Lung	LC-POC	187	0.96	0.86	80%	77%
	LC-600	628	0.85	0.80	80%	68%
BARD1 Ovarian	OC-POC	88	0.96	0.89	92%	84%
	OC-400	400	0.92	0.88	82%	79%

AUC is the accuracy of the test; Sensitivity is the % of people with cancer that correctly test positive; Specificity is the % people without cancer that correctly test negative.

Assay Development is required to develop and validate the technical performance of a commercial test on a suitable instrument platform to ensure accuracy and reliability. Studies are planned to further develop, optimise and technically validate the BARD1 Tests on a commercial platform in 2018.

Clinical Validation is then required to demonstrate the clinical performance of the BARD1 Tests for each intended use to enable marketing and licensing. Clinical studies will be planned to evaluate *BARD1-Lung* for early detection of lung cancer in high-risk asymptomatic individuals compared to LDCT, and *BARD1-Ovarian* for early detection of ovarian cancer in high-risk women compared to CA125.

REGULATORY

Diagnostic tests are regulated as in vitro diagnostic (IVD) medical devices requiring pre-market review of quality, safety and performance validation data, and clearance/approval by regulatory authorities to allow marketing. The commercialization pathway for BARD1 Tests includes CE Marking in Europe, ARTG Listing in Australia, and FDA-clearance/approval or sale as Laboratory-Developed Tests (LDT) in the US.

INTELLECTUAL PROPERTY PORTFOLIO

BARD1 has established a strong intellectual property position covering various BARD1 DNA and protein sequences, methods of diagnosis and treatment, and use in multiple cancers. The patent portfolio comprises 5 patent families with multiple granted and pending patents across key marketplaces including the US, Europe and Japan. In addition, the algorithms are protected by trade secret.

LEADERSHIP TEAM

Chairman	Peter Gunzburg BCom Public company director with extensive corporate leadership, stockbroking, corporate advisory and capital raising experience
Executive Director & CSO	Dr Irmgard Irminger-Finger PD PhD Founder, co-inventor and internationally recognised expert in tumour biology cancer with over 100 publications
Non-Executive Director	Prof Geoff Laurent PhD FRCP(Hon) FRCPATH FMedSci Organisational leader, thought-leader, scientific editor, SAB member and award-winning respiratory scientist with over 300 publications
Non-Executive Director	Brett Montgomery Public company director with leadership, operational, corporate governance and risk management experience
CEO	Dr Leearne Hinch BVMS MBA Biotechnology executive and consultant with strong leadership, operational, business development and commercial experience
Company Secretary	Pauline Collinson Experienced public company secretary

ACHIEVEMENTS & ANTICIPATED MILESTONES (CY)

1H18	✓Results of OC-400 Study for BARD1-Ovarian
	✓Japanese patent granted
	✓Additional BARD1-Ovarian test results
	○Commence additional development studies for BARD1-Ovarian
2H18	○Commence additional development studies for BARD1-Lung
	○Results of Technical Validation of BARD1 Tests
	○Results of Cancer Vaccine animal efficacy studies
2019	○Commence first Clinical Validation study for BARD1 Test

PARTNERING & INVESTMENT OPPORTUNITIES

BARD1 is seeking investors and commercialisation partners for its current diagnostic programs, and welcomes interest from potential partners to discuss collaboration or strategic alliance opportunities to expand the diagnostic and therapeutic potential of the BARD1 technology. Partnering opportunities include:

- **Strategic investment** to fund the ongoing development and commercialisation of the BARD1 product pipeline
- **Commercialisation** partners for BARD1 Tests for lung and ovarian cancer in the US, Europe, and AsiaPacific
- **Diagnostic collaborations** to evaluate and develop BARD1 Liquid Biopsy tests for diagnosis of cancer
- **Co-development** partners for evaluation and development of BARD1 Companion Diagnostics for targeted therapeutics
- **Therapeutic collaborations** to evaluate the therapeutic potential of the BARD1 Technology