

SHAREHOLDER UPDATE

Perth, Australia, 28 June 2017: Australian biotechnology company BARD1 Life Sciences Limited (ASX:BD1) (**BARD1 LSL** or the **Company**) today provided the following update on its business strategy, status of its development programs, and plans for further development and validation of the BARD1 Tests.

The Directors of BARD1 Life Sciences Ltd remain committed to realising the commercial potential of the BARD1 technology, advancing its diagnostic and therapeutic projects towards key development milestones, and growing shareholder value. Current research and development (R&D) plans are aimed at further research, development and analytical validation of the BARD1 Tests on a suitable instrument platform, before entering clinical validation. The planned studies, costs and timetable are as follows:

- BARD1 Lung Cancer Test
 - \$300K research study Sep 2017 - Dec 2017
 - \$800K assay development studies commencing H1 2018
- BARD1 Ovarian Cancer Test
 - \$150K research study Sep 2017 - Dec 2017
 - \$400K assay development studies commencing H2 2018
- BARD1 Cancer Vaccine
 - \$300K second stage *in vivo* tumour study Oct 2017 - Jul 2018

The Company will keep the market updated on its progress and results, and provide further details on its future clinical validation studies and commercialisation plans as its pipeline programs reach expected development milestones.

Research and Development (R&D) update

Lung Cancer Program

BARD1 LSL initiated a retrospective Lung Cancer Study in November 2016 to evaluate the performance of the multi-analyte BARD1 Lung Cancer Test on the Meso Scale Diagnostics (MSD) instrument platform in 638 samples of lung cancer and controls (LC600 study). The aim of the study was to evaluate the performance and limits of the BARD1 LC Test for detection of lung cancer across a range of lung cancer subtypes and stages. Initial statistical analysis of 480-samples showed an AUC (area under the curve) 0.82 for the best-fitted model and a predicted average AUC 0.725 in the test sets used to evaluate the model (see ASX announcement of 15/5/17). These results were lower than the performance achieved for the BARD1 LC Test in the Proof of Concept (POC) study that showed an AUC 0.96 for the best-fitted model and a predicted average AUC 0.86 in the test sets (see Table 1 below).

BARD1 LSL has completed its technical review of the LC600 study and has identified several technical factors that contributed to the reduced performance, including application of a new unoptimised assay method, unbalanced sample composition, and a possible gender influence. The outcomes of the study were:

- 1) Statistical analysis and modelling in 628-samples (containing additional healthy female controls) showed better accuracy with an AUC 0.85 for the best fitted model, and a predicted average AUC 0.80 in the test sets (see Table 1 below);
- 2) Statistical analysis and modelling by gender showed higher accuracy for a male-specific algorithm with an AUC 0.91 and a female-specific algorithm with an AUC 0.89; and
- 3) The 628-samples model showed high sensitivity across all lung cancer types and stages.

Dr Irmgard Irminger-Finger, Executive Director and CSO at BARD1 LSL, concluded, “Based on the LC600 study, we identified certain methods, selected analytes, and a gender influence that should enable us to develop a more accurate BARD1 Test for detection of lung cancer based on gender-specific algorithms.”

A summary of the lung cancer diagnostic performance results achieved in studies to date including AUC, sensitivity and specificity is provided in Table 1.

Table 1: BARD1 LC Test results

Study	Samples Nr (cancer:normal)	Best Fitted Model			Test Sets		
		AUC	Sensitivity*	Specificity*	Ave AUC	Sensitivity*	Specificity*
LC POC Study ¹	187 (94:93)	0.96	90%	85%	0.86	80%	77%
LC600 Study ²	480 (379:101)	0.82	76%	77%	0.72	65%	74%
	628 (395:233)	0.85	80%	78%	0.80	80%	68%

* The best **cut-off** that maximizes sensitivity and specificity

BARD1 LSL is working with industry experts to finalise a study design to confirm the POC results and improve the accuracy of the multianalyte BARD1 LC Test for detection of lung cancer across lung cancer types, stages, and patient origins and gender. This retrospective lung cancer study is planned to be conducted at the University of Geneva (UNIGE) laboratory facilities to evaluate the performance of the BARD1 LC Test in up to 1000 samples of lung cancer and controls using the original assay method applied in the POC study. The aims of the study will be to: 1) increase the accuracy of the BARD1 Test to detect lung cancer and meet minimum performance criteria, and 2) optimise the analyte combination, gender-specific diagnostic algorithm, and performance of the BARD1 LC Test for detection of lung cancer across different lung cancer types and stages. Additionally, the Company will investigate and identify suitable instrument platforms for further development and validation of the BARD1 LC Test. The planned research study is expected to commence in Sep-17, take 4 months to complete, and cost A\$300K.

Upon successful completion of the research phase, the lung cancer program will advance to the assay development phase to further develop, optimise and validate the analytical performance of a standardised BARD1 LC Test on the preferred instrument platform. The planned assay development studies are expected to commence in early 2018, take up to 12 months to complete, and cost under A\$800K.

Upon successful analytical validation of the standardised assay, the lung cancer program will advance to the clinical validation phase. Prospective clinical studies will then be undertaken to validate the clinical performance of the BARD1 LC Test for early detection and screening of lung cancer in high-risk asymptomatic individuals compared to the current gold standard CT scans.

The BARD1 Lung Cancer (LC) Test is an ELISA-based blood test in development for screening and early detection of lung cancer. The test measures multiple BARD1 autoantibodies in the blood and uses a proprietary diagnostic algorithm to combine these levels into a cancer score that identifies the presence or absence of lung cancer. The BARD1 Lung Cancer Test could potentially be used as a screening test for early detection of lung cancer in high-risk asymptomatic individuals, as a diagnostic aid for lung cancer in people with symptoms, or to assess the risk of malignancy in people with indeterminate pulmonary nodules following a CT scan.

Ovarian Cancer Program

BARD1 LSL initiated a retrospective Ovarian Cancer Study in January 2017 to evaluate the performance of the multi-analyte BARD1 OC Test on the MSD instrument platform in 348 female samples of ovarian cancer and controls (OC300 study). The aim of the study was to evaluate the performance and limits of the BARD1 OC Test for detection of ovarian cancer across a range of ovarian cancer subtypes and stages. The study showed high accuracy of the best fitted model generated on 348 samples, achieving an AUC 0.92, sensitivity 90%, and specificity 87% (see ASX announcement of 23/3/17). Additionally, the predictive performance of the model applied in test sets showed an average AUC 0.85, sensitivity 78%, and specificity 78%.

Dr Irmgard Irminger-Finger said, "These ovarian cancer results confirmed the POC study results, with high accuracy achieved across all types and stages of ovarian cancer, and demonstrated the potential of the BARD1 OC Test for early detection of ovarian cancer."

A summary of the ovarian cancer diagnostic performance results achieved in studies to date including AUC, sensitivity and specificity is provided in Table 2.

¹ Pilyugin et al. BARD1 serum autoantibodies for early detection of lung cancer. Jan 2017. (Submitted to peer reviewed journal for publication, awaiting acceptance)

² BARD1 LSL. Data on file. May 2017.

Table 2: BARD1 Ovarian Cancer Test results

Study	Samples Nr (cancer:normal)	Best Fitted Model			Test Sets		
		AUC	Sensitivity*	Specificity*	Ave AUC	Sensitivity*	Specificity*
OC POC Study 1 ³	116 (58:58)	0.86	81%	80%	0.75	68%	65%
OC POC Study 2 ⁴	88 (44:44)	0.96	92%	90%	0.89	92%	84%
OC300 Study	348 (200:148)	0.92	89%	88%	0.85	78%	78%

* The best **cut-off** that maximizes sensitivity and specificity

BARD1 LSL plans to undertake further research, development and validation of the BARD1 OC Test to optimise diagnostic performance across ovarian cancer types and stages. The research phase to further optimise the multianalyte assay and its performance is expected to commence in Sep-17, take 4 months and cost under \$150K. The development phase to develop and analytically validate a standardised BARD1 OC Test is expected to take up to 6 months, cost under \$400K, and run parallel to the BARD1 LC Test as a similar assay method and instrument platform will be applied. Prospective clinical studies will then be undertaken to validate the clinical performance of the BARD1 OC Test for detection of ovarian cancer in high-risk asymptomatic women.

The BARD1 Ovarian Cancer (OC) Test is an ELISA-based blood test in development for detection and monitoring of ovarian cancer. The test measures multiple BARD1 autoantibodies in the blood and uses a proprietary diagnostic algorithm to combine these levels into a cancer score that identifies the presence or absence of ovarian cancer. The BARD1 OC Test could potentially be used as a screening test for early detection of ovarian cancer in high-risk asymptomatic individuals, as a diagnostic aid for detection of ovarian cancer in women with pelvic masses, or to monitor ovarian cancer recurrence.

Cancer Vaccine Program

BARD1 LSL recently entered into a collaboration agreement with the Institute for Respiratory Health (IRH) to evaluate a potential BARD1 cancer vaccine for the prevention and/or treatment of cancer in animal models (see ASX announcement of 5/4/17). The cancer vaccine program is on-track with initial research underway at the IRH to identify high BARD1 expressing tumour cell lines for implantation in animals, and obtain Animal Ethics Committee approval from UWA for animal studies. The second stage of the study will evaluate the in vivo effectiveness of the BARD1 vaccine formulations for reducing tumour growth in animal studies. This stage is expected to commence in Oct-17, take up to 10 months to complete, and cost an additional A\$300K.

Financial Update

The Company's closing cash balance at 23/06/2017 was \$671K.

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³ BARD1 LSL. Data on file. Sep 2016.

⁴ BARD1 LSL. Data on file. Dec 2016.

Notes to editors:

ABOUT BARD1 LIFE SCIENCES LTD (BARD1 LSL)

BARD1 Life Sciences Ltd (ASX:BD1) is an Australian biotechnology company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer. Its lead product, the BARD1 Lung Cancer Test, is a blood test in development for early detection of lung cancer, utilising novel tumour markers and a proprietary algorithm. The company's pipeline also includes the BARD1 Ovarian Cancer Test in development for early detection of ovarian cancer, and high-value diagnostic and therapeutic projects at research-stage for multiple cancers. BARD1 LSL is committed to transforming the early detection and prevention of cancer to help improve patients' lives.

ABOUT THE BARD1 TECHNOLOGY PLATFORM

The proprietary BARD1 Technology includes BARD1 tumour markers, diagnostic assays and algorithms. BARD1 tumour markers have potential utility as 1) diagnostic biomarkers for the detection and monitoring of cancer, and 2) therapeutic targets for immunotherapies that inhibit abnormal BARD1 for the prevention or treatment of cancer. The BARD1 Technology has potential applications across multiple cancers including lung, breast, ovarian, prostate, and colorectal cancer.

BARD1 is both a gene and a protein that play an important role in the normal cell cycle and tumour suppression. However, cancer cells express numerous abnormal BARD1 proteins that drive oncogenesis (cancer formation), and are correlated with cancer progression and poor prognosis. Abnormal BARD1 proteins are immunogenic and induce circulating BARD1 autoantibodies in the blood. These abnormal BARD1 proteins (tumour-associated antigens) and autoantibodies are tumour markers that can be found in the blood of people with various cancer types and stages from early to late.

ABOUT DIAGNOSTIC TEST TERMINOLOGY AND PERFORMANCE MEASURES

What is an ELISA test? Enzyme-Linked Immunosorbent Assay (ELISA) is a biochemical method used to detect the presence of an antibody or antigen in a liquid sample. ELISAs are the most widely used assay type, as it is a relatively fast and inexpensive test method.

What is a ROC curve? A receiver operating characteristic (ROC) curve graphically shows the performance of a diagnostic test by plotting the true positive rate (TPR or sensitivity) for correctly detecting cancer in diseased patients against the false positive rate (FPR, or 1-specificity) for incorrectly identifying cancer in non-diseased (healthy) patients, at various threshold settings. A ROC curve can be used to evaluate the diagnostic performance of a single test, or to compare diagnostic tests. A good diagnostic test must demonstrate a high sensitivity (correct diagnosis) and acceptable false positive rate (cancer scares) for the disease.

What is ROC analysis? Statistical evaluation of diagnostic performance involves developing a diagnostic algorithm (or model) for all samples in a study to generate an in-sample AUC result, and then (if small sample numbers) cross-validating the algorithm by repeated random splitting of the samples (200-500 times) into training sets to fit the algorithm (using approximately 2/3 of the samples) and separate test sets to evaluate the predictive performance of the algorithm including out-of-sample average AUC, sensitivity and specificity (remaining 1/3 of samples).

What is the AUC? The area under the curve (AUC) is an index of accuracy of a test in distinguishing between patients with and without cancer, where the greater the AUC the better the test. A perfect test would have an AUC=1.0, an excellent test AUC=0.9-0.99, good test AUC=0.8-0.89, fair test AUC=0.70-0.80 and a useless test AUC=0.5 (same probability as chance). An AUC=0.90 means there is a 90% probability that a randomly chosen diseased patient will have a higher score than a randomly chosen healthy patient.

What is sensitivity? Sensitivity (or true positive rate) is the percentage of patients with cancer that were correctly identified with a positive test result. High sensitivity is important because it minimises the number of patients with cancer that are missed (false negatives). For example, if a test has a sensitivity of 90% for lung cancer, then it detects 90% of people with lung cancer and misses lung cancer in 10% of people with cancer.

What is specificity? Specificity (or true negative rate) is the percentage of patients without cancer that were correctly identified with a negative test result. For example, if a test has a specificity of 90% for lung cancer, then 90% of healthy people will correctly test negative and the other 10% will be false positives.

What is a false positive? False positive (1 - specificity) is the percentage of healthy people without cancer that were incorrectly identified with a positive test result. A diagnostic test with low specificity for cancer may have an unacceptably high false positive rate (“cancer scares”) that can lead to patient anxiety and over referral of healthy individuals for unnecessary invasive and costly follow-up procedures.