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BARD1 Life Sciences Ltd (ASX Code: BD1)

Recommendation: Strong Buy (Speculative) at A$0.027 per share

Market Capitalisation: 552 m shares @ A$0.027 per share = <u>just A$14.0M</u>

Target Price (Preliminary) – Our preliminary target price is A$0.09 – based on a targeted A$50M mkt cap.

BD1 is developing a biomarker for early detection of lung cancer by way of a standard blood test.

State One believes that Bard1 has the potential to enjoy a significant rise in its share price over the next six months. This will be achieved, firstly by having the US-based Meso-Scale independently validate and optimise the initial tests results already obtained by Dr Irminger and her team at the UNIGE lab; and secondly by increasing the sample size three fold after the delivery of an additional 450 blood samples. During this six month period it is expected that Dr Irminger's scientific paper should also be reviewed and published in the scientific world.

The steps in identifying and curing lung cancer using Bard1 are seen as:

1. Obtain Independent confirmation that the Bard1 gene is an appropriate biomarker for the early stages of lung cancer.
2. Test an increased blood sample size against Bard1, to confirm whether or not cancer presence is suggested.
3. Develop an appropriate methodology for treatment where cancer is suggested.
4. Produce a vaccine.

Note: Bard 1 management believes that they have developed a "best in class" diagnostic tool to identify early-stage lung cancer. Now, they will have to convince their peers, through presenting the results to the cancer research community. This is due to occur before the end of December 2016.

BD1 SHARE PRICE HISTORY & COMMENT

BARD1 Life Sciences Ltd (ASX: BD1) listed on ASX on 20th June 2016, after being re-birthed from its former life as ASX-listed Eurogold Limited in a Public Offer of 150 M ordinary shares @ A$0.02 per share to raise $3.0M, pursuant to a Prospectus lodged with ASIC. The offer was lead managed by State One Equities Pty Ltd. The $3.0m in net cash held as at 30 June 2016 is reckoned to be sufficient to meet BARD1's funding requirements for two full years, i.e. until 30 June 2018.

BD1 has been back on the boards for some 3 months now. Already, it has established a decent price base, and volumes have ranged between 20 M and 85 M shares per month. We are confident of further share price strength as market awareness grows as the date of publication of new data approaches.

Bard1 Share Price on ASX (June 2016 to Present)

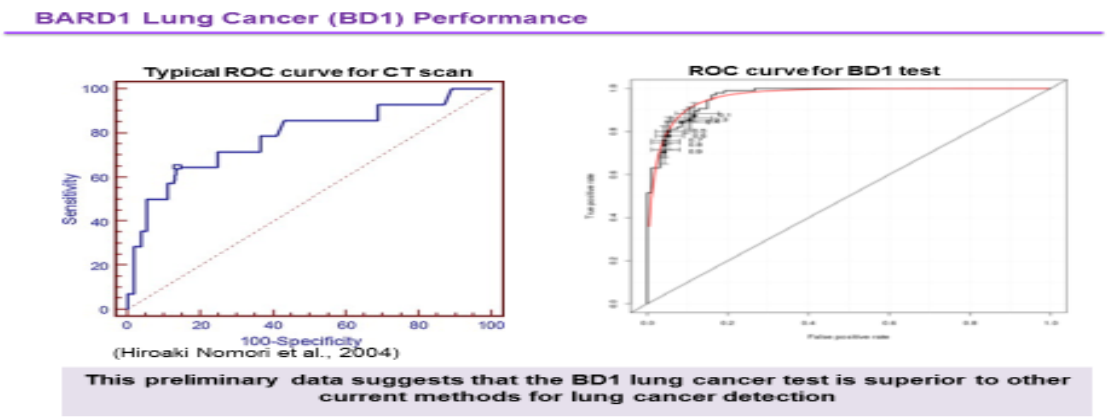
KEY POINTS

- The Bard1 management team is led by the widely proclaimed molecular biologist / scientist, Dr Irmgard Irminger-Finger (Executive Director). She has been the recipient of a multitude of awards for her work, over +20 years. Irmgard has spent more than 15 years researching cancer and the Bard1 gene, from her base at the University of Geneva ("UNIGE") and the University Hospital of Geneva ("HUG").
- Bard1 has declared that it is well advanced in developing an accurate, low cost and easy to complete blood test for identifying the early stage presence of lung cancer (and potentially other cancers).
- **Following the recent appointment of US-based Meso Scale Diagnostics, the global leader in biological sample assaying, Bard1 has indicated that by the end of CY 2016, they should be able to deliver fully validated and optimised results for the 200 samples already tested. Once revised protocols have been confirmed by Meso Scale (targeted for end 2016), BD1 is targeting to have a further 450 samples validated by the end of the March 2017 quarter. We believe that, at this point, the potential of Bard1 will be fully evident.**
- **Bard1 has sufficient working capital for the next two years by which time its aim is to have have established a more accurate and cost effective lung cancer diagnostic test.**
- Bard1's marker has already achieved excellent statistical results in assessing whether or not the indicated presence of lung cancer is accurate. A basic measure of statistical accuracy used by Bard1 is called "under the curve" which has been recorded at 96% for Bard1, compared with just 70% for the well-known prostate-focussed PSA test (widely recognised as being effective, but also as having defects.). Bard1's aim is to make its Lung Cancer Test just as simple to conduct, and more effective, than the PSA test.

Other Cancer Forms Targeted:

- Early in 2017, BD1's evaluation technique is expected to be extended and applied to cover other cancer forms, including breast, colorectal and, most notably, ovarian cancer. Ovarian is of particular interest to Bard1, being similar to lung cancer in that the disease hits hard and fast, with little in the way of prior warning, and no evidence of disease until the symptoms show.
- Breast cancer is also of particular interest due to the fact that the cancer is in many cases readily visible which can aid diagnosis.
- In addition, pre-clinical tests indicate that BARD1 is immunogenic – i.e. capable of slowing tumour growth, raising the potential for the development of a vaccine for any of lung, ovarian, and possibly other forms of cancer at some point in the future.

In the 30 June 2016 quarterly report to shareholders BD1 described its first blood samples as delivering "Exceptional Preliminary Results." The results from the first samples are best illustrated by comparing them to the current industry standard as achieved with CT scans, as shown in the ROC curves below.



The ROC Curve measures the true positive sensitivity and the false positive sensitivity of the test. The closer to the diagonal the LESS accurate is the test. A paper describing these results in detail is currently being prepared by Bard1 for publication to the scientific community before the end of 2016.

INTELLECTUAL PROPERTY

Bard1 is confident that it has fully secured the IP relating to Bard1 through a series of patents spanning the major world countries. The primary IP is held by HUG & UNIGE both of whom have granted BARDIAG an exclusive license to use & exploit the rights to the technology. Bard1 must pay them a combined trailing commission of 2% of net sales. BARD1 has spent considerable effort enhancing the scope and integrity of its Intellectual Property surrounding the BARD1 protein. Based on some very preliminary data and the IP owned by BARD1, the Company now believes there is potential for BARD1 to act as an accurate biomarker for other cancers, including breast, ovarian and colon.

COMPANY OVERVIEW

- BARD1 has pioneered the development of a simple blood test for screening and diagnosing lung cancer at the early stages of the disease progression. (It is known as the "**BARD1AG Lung Cancer Test.**"). This simple, non-invasive and cost-effective test screens for and diagnoses cancers based on the presence of a particular "factor"- the gene (and protein) BARD1. The test is very similar to the widely applied 'PSA test', which has been an effective detector of prostate cancers since 1986.
- BD1 is the sole owner of BARD1AG, a Swiss public company founded in 2010 under the leadership of the CEO, Dr Irmgard Irminger.
- Irmgard is about as well-credentialed as anyone on the planet when it comes to gene research. For more than 15 years she has been focused almost solely on BARD1 research. During this period, she has lead a team which has ranged in size from between 4 and 10 people, comprising largely biologists, supported when required by medical doctors and statisticians. Dr Irminger and her team are estimated to have overseen expenditure of no less than US$10M in researching the Bard1 gene.
- Over the past 15 years, BARDIAG has cultivated many strategic partnerships which have the potential to rapidly expand the use and application of its test (once fully developed).
- While there have been other research teams investigating the BARD1 gene, Irmgard is rather famous for identifying that the presence of cancer cells makes for an aberrant form of the Bard1 gene, which is clearly identifiable as such.
- To develop the BARD1AG Lung Cancer Test beyond the "proof of principle" stage, it is now necessary to apply it in a clinical setting, and compare it with prevailing testing methodologies (primarily computed tomography or CT scans) to determine medical viability.

Risk versus Reward:

- BD1 is a business which, while not risk-free, offers the potential for both an incredible social benefit and a most exciting commercial return.
- Although BD1 should be considered as a higher risk company, as it commences its life as a listed entity with a negative cash flow, with a risk of loss on the original capital invested. In the authors' view, however, the project promises not to be a massive consumer of capital.
- Likewise, BD1's activities are not expected to involve any risk to patients whatsoever, and the path to regulatory approval seems almost totally devoid of major hurdles.
- It seems that BD1 is likely to offer a much more beneficial outcome for patients than the long established PSA test.

About Lung Cancer:

- Lung cancer is the third most frequently diagnosed cancer in both men & women. It accounts for 27% of all cancer deaths.
- The lung cancer market is reckoned to be at least as large as the PSA market, which is forecast at $US17.7 billion in 2017.-
- A key factor attributed to the high mortality rate of lung cancer is that diagnosis is in most instances only possible once a patient displays symptoms.
- The BARD1AG Lung Cancer Test offers the potential for a simple test, capable of routinely screening for and diagnosing cancer at an earlier stage in the progression of the disease.

Effectiveness & Costs of Testing:

- Medical testing is invariably expensive as it involves repetitive handling blood in a sterile environment. Not especially simple.
- Currently, these is no viable lung cancer testing regime comparable to that which Bard1 proposes to offer.
- The best alternative on offer is the CT SCAN, (computerised tomography) which is very expensive with a cost of about $2,000 per session.
- Bard1 would suggest that its test will initially involve a cost much lower than that and, as volumes grow, costs will decline.
- *Evaluation of the testing techniques employed by Bard1 suggests that not only is it highly competitive against other techniques with regards to cost, it is far more accurate when compared with say PSA.*
- Accurate readings clearly reduce significantly the overall cost of sample testing.
- It is expected that future operating costs will include the (reduced) cost of a new optimised testing method applied by Mesoscale, a US company with world-leading expertise in sampling, which has recently been retained by BD1. Mesoscale is planning to apply its techniques in a first batch of Bard1 samples, to be tested before the end of 2016.
- It is proposed that the required full batch of 2,000 samples will be collected from cancer patients undergoing CT scans at the University College London (already confirmed as being cancer positive), in the period to the end of December 2017.
- Through the next 18 months we also expect to see preliminary Bard1 testing applied to patients with preliminary indications of breast and ovarian cancer.

BARD1 DIRECTORS

- **Mr Peter Gunzburg (Executive Chairman):** **Mr Brett Montgomery (Non-Executive Director)**
- **Dr Irmgard Irminger-Finger (Executive Director):** Head of the Molecular Gynecology and Obstetrics Laboratory at UNIGE and UHG, and founder of BARD1AG. Irmgard is responsible for more than 40 publications on BARD1 and cancer. She is the largest shareholder in BARD1. (The University of Geneva is the fifth largest.)
- **Professor Geoffrey Laurent, (Non-Executive Director)** PhD, FRCP(Hon), FRCPath

  Professor Laurent is the Director of the Institute for Respiratory Health and Director of the Centre for Cell Therapy and Regenerative Medicine at UWA. Prior to these appointments he was Head of Department of Internal Medicine and Director of the Centre for Respiratory Research at University College London. He was awarded the European Respiratory Societies Presidential Award for his contribution to lung science. He is Editor-in-Chief of the International Journal of Biochemistry and Cell Biology and has published over 250 peer reviewed articles in international journals of biomedical research.

CAPITAL STRUCTURE

Issuer	**Bard1 Life Sciences Ltd (ACN 009 070 384)** (ASX code: BD1)
Recent Offer	Full Subscription A$3.0 million
Offer Price	A$0.02 per share
Securities	Fully paid ordinary shares
Capital Structure.	Pre- Offer shares: 172 m Issued in Public Offer: 150 m Issued to the Vendor: 217 m Issued to HUG & UNIGE: 12.5 m **Total Shares on issue** - completion of the Offers: **552 m** --- Potential additional performance shares subject to achieving certain milestones. **217 m**
See conversion terms overleaf.	
Market Cap.	A$14 million ($0.027)

USE OF CAPITAL – RECENT OFFER

Recent Capital Raise

Max. number of Securities under the offer 150 million
Subscription price per share A$0.02
Maximum gross proceeds from the Offer A$3 million

Use of Capital

1. Assist BD1 with re-admission to the ASX,
2. Fund Planned Further Study and to develop and exploit the BARD1AG intellectual property, and
3. Provide BD1 with additional working capital for its current and future expanded business.

HOW BIG IS THE GLOBAL CANCER MARKET

- The American Cancer Society (ACS) has estimated that more than 12 million new cases of cancer are diagnosed worldwide each year. State One reckons that it is reasonable to estimate that perhaps about one quarter of these are lung cancer.
- Overall cancer leads to more than 6 million deaths worldwide each year.

BARD'S BUSINESS MODEL

Significantly increase the clinical trial - to not less than a further 200 patients and compare outcome to prevailing testing methodologies in terms of accuracy of predicting cancer presence. ("Planned Further Study")

Demonstrate that the performance of the BARD1 test in a clinical setting is better than the current "gold standard" (the CT Scan) for lung cancer testing and diagnosis, and

Commercialise the BARD1AG Lung Cancer Test, through either:

- licensing of the method to prospective partners. These could include any of: diagnostic companies, ELISA-based platform providers, CT-scan providers and clinical diagnostics labs. or
- Alternatively, secure a trade sale to a pharmaceutical company or medical device manufacturer.

Depending upon the results of the Planned Further Study, BARD1AG may also seek to develop the Lung Cancer Test for other cancers and seek to further commercialise the Test for the testing of other cancers.

KEY INVESTMENT RISKS

In undertaking its business activities, BD1 will be exposed to risks, which include, but are not limited to:

- Successfully completion of the "Planned Further Study",
- Successfully commercializing the BARD1AG Intellectual Property and maintaining all Intellectual Property protection,
- Meeting future capital needs,
- Maintaining the services of key employees (esp. Dr Irminger),
- Competition within the highly competitive and rapidly evolving cancer diagnostic industry,
- Complying with all needs imposed by regulators.
- General securities and share market conditions.

CONVERSION TERMS FOR 217 M PERFORMANCE SHARES

Each Vendor Performance Share will convert into one Share upon the satisfaction of a **Milestone** prior to the **Expiry Date** (five years from the date of issue).

The Milestone is an announcement to ASX that:

- The clinical trial of the blood test developed by BARD1AG S.A. for the detection of lung cancer (BBLC Test) has been completed;
- The clinical trial involved at least 2,000 participants within no more than 2 years, and returned a detection rate greater than 80%, and false positive results of less than 20%; and

- It is not hard to pin-point where the trouble spots are. For example, it is a well-known fact that smoking is the key source of cancer in the Western World. In the east, in particular, pollution is a major cause.

- The total prostate cancer market value is expected to reach $50.3 billion in 2017 after increasing at a five-year compound annual growth rate (CAGR) of 11.4%.

- With regards to prostate cancer, diagnosis and screening market is expected to be $17.4 billion in 2017, with a CAGR of 7.5% in recent years.

  The market for lung cancer is reckoned to be of similar

- The results of the clinical trial provide statistically significant evidence that the BBLC Test provides an outcome equal or superior to the current "gold standard" computed tomography x-ray scan (CT scan), which has a detection rate of less than 80%, and returns false positive results of no more than 20%.

Note: If the Milestone is not met by 5.00pm (Perth time) on the Expiry Date, the Company will, as soon as reasonably practical convert the total number of Performance Shares on issue into one Share. IT IS NOT EXPECTED THAT THIS WILL HAPPEN

Analysts: Alan Hill & David Brennan *7th Sept. 2016*

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APPENDIX: PEER COMPARATIVE

A peer comparative to Bard1 is UK-based **Oncimmune Holdings PLC** (LON: ONC). ONC listed on London's AIM (Alternative Investment Market) in mid-May 2016 via a £11m (~ A$19m) IPO. ONC, like BARD1, has developed a test for early cancer detection.

ONC: Background & Strategy

- Oncimmune Limited was incorporated in 2002 as a spin out from the University of Nottingham, and spent several years developing its proprietary *Early***CDT®** blood tests before gaining proof of concept in 2005. (CDT = Cancer Detection Test) Note that the CDT tests are based on the presence of auto-antibodies which form in response to abnormal host molecules (tumor associated antigen). (Quite a different approach to that of Bard1.)
- In 2007, Oncimmune USA opened its North American operational headquarters including a 1,000m^2 laboratory and associated commercial support in Kansas, USA. In 2009, ONC USA gained CLIA accreditation for this laboratory and launched its first test, *Early***CDT®-Lung**, which was test-marketed until 2012.
- In 2012, Oncimmune USA launched its *Early***CDT®-Lung** test nationally across the US; **over 140,000 commercial tests have since been sold and carried out in the group's +2 million tests per annum capacity laboratory** (where all *Early***CDT®-Lung** tests are performed).
- The next phase for **ONC** is the execution of its commercial growth strategy. Funds raised from the recent listing (A$19M) will be used for product development and to advance the commercial infrastructure required to accelerate and deliver its growth strategy.
- In May 2016, ONC announced that it had entered into three distribution agreements in the US for its *Early***CDT®-Lung** tests. The agreements have been signed with national and regional distributors and will increase the total salesforce to more than 140 across the US. ONC now has distribution agreements covering the major US markets and is in discussions with several other distributors.
- Additionally, in June 2016 ONC announced that it had signed Ovarian and Liver Cancer research agreements with Egybiotech, a private research company with a broad research portfolio in the areas of cancer research, and with Aarhus University Hospital ("Aarhus"), in Denmark.
- Selected financial data (for year ending 31 May 2015): Revenue £1.35m, Operating Loss -£1.38m, NLAT -£2.0m, Total Assets £1.95m, Total Liabilities £5.8m.

State One comment:

ONC is clearly more advanced than BARD1 in terms of basic product development and commercialization, as BARD1 was only founded and started first developments in 2010.

Nevertheless, in a technical sense BD1 appears to be the more advanced of the two, as it already has a test which is a substantially more accurate test than that of ONC, and we understand every other player in that space. With reference to our earlier comments, it appears that ONC has either not yet produced a reliable ROC curve.

Based on 51m total shares in issue (excluding 6.4m options/warrants) and at ONC's current share price of £1.17, ONC is valued at some £60m (A$104m). Note: With a M'Cap of £60m, and historical operating losses, the market is discounting strong revenue & profit growth from Oncimmune. On the other hand BD1 is currently free of debt with about A$3.0m cash.

In State One's view the "value gap" between the two companies seems extreme. BARD1 - with what we deem to be a superior technology - and a market cap. of some A$17m, versus ONC's market cap of about A$104m.
