



# BARD1 Life Sciences (ASX: BD1)

## Lung Cancer Test setback delays path to clinical validation

17 May 2017

### Event

On 15 May 2017, BD1 announced the results of a 638-sample lung cancer study using its BARD1 Lung Cancer Test. The study demonstrated that the Test had an overall ROC-AUC score for accuracy in identifying lung cancer of 0.82 in the training sets and 0.725 in the test sets.

BD1 is working with external consultants to determine the underlying issues behind the lower than anticipated results; the group now plans to optimise the assay and evaluate the test's analytical performance before proceeding with further clinical validation. As a result, BD1 advises that the planned clinical validation studies for the BARD1 Lung Cancer Test and BARD1 Ovarian Cancer Test will be delayed.

In response to the announcement, BD1's share price fell some 53% to close on 15 May at A\$1.7c (from A\$3.6c on 12 May 2017). BD1's share price has since fallen a further 18% to A\$1.4c (close 16 May).

### State One comments: Target price reduced to A\$1.9cps (A\$6.5cps previously)

- The results are an undoubted setback.
  - The Lung Cancer Test training set ROC-AUC score of 0.82 is disappointing relative to the BARD1 Lung Cancer Test proof-of-concept score of 0.96, and the February 2017 Assay Feasibility Study performed by Meso Scale Diagnostics which achieved a score of 0.93. The score was also significantly below the March 2017 Ovarian Cancer Test training set score of 0.92.
  - The marked variance between the training set score of 0.82 and the test set score of 0.725 is problematic. Note: the test set score of 0.725 is similar to (but does not improve on) the current "gold standard" for lung cancer detection - computed tomography (CT) scans – which typically have ROC-AUC scores in the low 70s.
- We believe that transferring the BARD1 assay to a new instrument platform (involving numerous assay changes), combined with testing a broader patient cohort, was too ambitious for the early development stage of the BARD1 Test. Management is now focused on reviewing the assay design, the suitability of the new instrument platform and validating the analytical performance of the Test (i.e., determining the assay's reliability and accuracy), rather than the diagnostic performance of the test (i.e., disease diagnosis).
- Management has not, as yet, provided a timeline for how long this investigation and any further assay development will take; however, we believe that whatever the underlying assay issues are, the research-grade BARD1 Lung Cancer Test will have to be repeated. We hope repeating the study by eliminating the already identified negative changes will generate better results.
- As a result, we estimate that BD1's initial target of having a clinical study on its BARD1 Lung Cancer Test completed by mid-2018, with commercialisation in 2019, could be delayed by between 6 and 12 months.
- Based on March (actual) and June (estimate) 2017 quarter cash flows, we estimate this project slippage could require BD1 to require additional funding for working capital and R&D of at least A\$1m.

**VALUATION:** Because of the Lung Cancer Test set-back, we now attach a 66% risk-discount to our initial indicative valuation for BD1 of A\$50m (note: valuation based on m'caps attached to overseas peers in the in vitro diagnostic space). **Our revised risk-adjusted valuation for BD1 is A\$17m or A\$1.9c per forecast fully diluted share** (forecast 864m shares = 769m current fully diluted shares + 95m new shares assuming a A\$1m capital raising at A\$1.05cps (25% discount to current A\$1.4c share price)). Although the project slippage is disappointing, we maintain our view that BD1 still has the potential to offer speculative investors exciting commercial returns.

*Background: ROC-AUC score = Receiver Operating Characteristic – Area Under Curve score. These are statistical measures of true positive rate against false positive rates, with the greater the AUC the better the test. In a clinical context, an AUC of 0.90 means the probability of correctly classifying a patient as being positive or negative for cancer is 90%.*

## Warnings and Disclosures

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*Note: State One Stockbroking was Lead Manager in BD1's A\$3m capital raising in June 2016.*

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