

Rules 4.3A

Appendix 4E

Preliminary final report

Name of entity

BARD1 Life Sciences Limited

ABN or equivalent company
reference

58 009 070 384

Year ended ('current period')

30 June 2018

12 months ended ('comparative
period')

30 June 2017

Results for announcement to the market

\$AUD

Revenues from ordinary activities	Up	42%	To	62,418
Loss from ordinary activities after tax attributable to members	Down	31%	To	(1,783,906)
Net loss for the period attributable to members	Down	31%	To	(1,783,906)
Dividends (distributions)	Amount per security		Franked amount per security	
Interim dividend	Nil		- ¢	
Final dividend	Nil		- ¢	
Previous corresponding period	Nil		- ¢	
+Record date for determining entitlements to the dividend, (in the case of a trust, distribution)	N/A			

The above results should be read in conjunction with the notes and commentary contained in this report.

OPERATING RESULTS

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+ See chapter 19 for defined terms

The Group has reported a loss from ordinary activities for the year of \$1.8m (2017: net loss \$2.6m), driven by Research and Development (R&D) expenditure of \$770.8k on the BARD1 pipeline, patent expenses of \$180.9k, and staff, corporate and administration costs of \$1.2m. The Group received a Research and Development Tax Incentive (RDTI) refund of \$210.7k including \$94.9k for the 2016 financial year and \$115.8k for the 2017 financial year. The closing cash balance at 30 June 2018 was \$1.5m.

The loss per share of the Group for the full-year ended 30 June 2018 was 0.26 cents per share (2017: 0.45 cents per share).

OPERATIONAL REVIEW

BARD1 Life Sciences Ltd (**ASX:BD1**) is an Australian-based biotechnology company focused on developing and commercialising non-invasive diagnostics for early detection of cancer. During the 2018 financial year, there were a number of important research and corporate developments:

Research

- **Advanced Ovarian Cancer Program:** Completed OC-400, OC-400V and OC-CA125 studies to further develop and optimise the BARD1-Ovarian test with the addition of the CA125 biomarker improving accuracy to 88% sensitivity and 93% specificity.
- **Publication of lung cancer results:** Publication of POC study results for BARD1-Lung in international peer-reviewed journal PLOS ONE.
- **Progressed Cancer Vaccine Collaboration:** Completed Stage 1 of the Cancer Vaccine Collaboration with the IRH and commenced Stage 2 to evaluate its effectiveness for reducing tumours in animal models.
- **Transfer of BARD1 assay to Luminex® platform:** Signed Assay Development Agreement with Thermo Fisher Scientific to develop a RUO multiplex BARD1 autoantibody assay using ProcartaPlex® Technology for performance on Luminex® instrumentation.

Corporate

- **New patents granted:** Several patents granted in two key patent families protecting the BARD1-Lung test in Australia, Japan and Israel, and the BARD1-Ovarian test in the USA.
- **Advisory Board Appointment:** Appointment of Dr Samuel Janes MBBS MRCP MSc PhD to the BARD1 Advisory Board.
- **Capital Raisings:** Successful completion of Placements and Share Purchase Plan (SPP) to raise \$2.8m.

Ovarian Cancer Diagnostic Program

BARD1 plans to develop BARD1-Ovarian as an accurate and reliable screening test for early detection of ovarian cancer, the leading cause of gynaecological cancer death in women. During the year, BARD1 LSL completed several important ovarian cancer studies to further develop and optimise the BARD1-Ovarian test.

On 9 January 2018, BARD1 announced positive results from its **OC-400 Study** to evaluate the accuracy of the BARD1-Ovarian test to detect ovarian cancer in 400 samples of ovarian cancer and healthy controls. The results demonstrated that BARD1-Ovarian could accurately detect ovarian cancer with 82% sensitivity and 79% specificity in cross-validation test sets.

On 6 March 2018, BARD1 announced additional positive results from a follow-on **OC-400V Study** to evaluate the robustness of BARD1-Ovarian in an independent test set of 82 new ovarian cancers and 27 previously tested healthy controls. The results showed high accuracy for detection of ovarian cancer with 89% sensitivity and 82% specificity in the independent test set.

On 18 May 2018, BARD1 announced it had signed an Assay Development agreement with Thermo Fisher Scientific to transfer its research assay to the Luminex® platform to speed further development and validation activities. Development of the new multiplex BARD1 autoantibody assay using ProcartaPlex® Technology for performance on Luminex® instrumentation will enable the Company to transfer its ongoing research and development activities for BARD1-Ovarian, BARD1-Lung and other diagnostic applications to an Australian laboratory that will potentially increase its access to the Australian Government's RDTI.

On 19 June 2018, BARD1 announced positive results from its **OC-CA125 Study** to evaluate and compare the accuracy of the original BARD1 algorithm alone, CA125 alone, and the combined BARD1-CA125 algorithm to detect ovarian cancer in 200 ovarian cancers and 200 healthy controls. The results demonstrated that the accuracy of the BARD1-Ovarian test was significantly improved by addition of the CA125 cancer biomarker with an AUC 0.95, 88% sensitivity and 93% specificity for detection of ovarian cancer.

Upon successful completion of the Assay Development project to transfer the research BARD1 assay to Luminex® instrumentation, BARD1 intends to conduct clinical studies in 2019 to evaluate the clinical performance of BARD1-Ovarian for early detection of ovarian cancer.

Lung Cancer Diagnostic Program

BARD1 plans to develop BARD1-Lung as an accurate and reliable screening test for early detection of lung cancer, the leading cause of cancer death in men and women. Previous research including the LC-POC Study and the LC-600 Study demonstrated the potential of further developing BARD1-Lung as a highly sensitive and specific blood test for early detection of lung cancer using additional biomarkers and gender-specific algorithms.

On 7 August 2017, a key paper on the original lung cancer POC Study results and underlying scientific methodology for the BARD1-Lung test was published in international peer-reviewed journal *PLoS ONE*. The paper titled 'BARD1 serum autoantibodies for early detection of lung cancer' describes a simple and reliable blood test for early detection of all types of lung cancer based on the immunogenicity of aberrant forms of BARD1 protein that are upregulated in lung cancer.¹

Continuation of the lung cancer program is currently planned upon successful transfer of the BARD1-Ovarian test to the Luminex® platform. Further case-control studies are planned for 2019 to optimise the BARD1-Lung test using the new multiplex BARD1 assay, additional biomarkers and gender-specific algorithms, followed by development and analytical validation of the refined BARD1-Lung on Luminex® instrumentation, before advancing towards clinical studies.

¹ Pilyugin M, Descloux P, André P-A, Laszlo V, Dome B, Hegedus B, et al. (2017) BARD1 serum autoantibodies for early detection of lung cancer. *PLoS ONE* 12(8): e0182356. <https://doi.org/10.1371/journal.pone.0182356>

Cancer Vaccine Program

BARD1 has a research collaboration 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.

On 4 October 2017, BARD1 advised that Stage 1 of the Cancer Vaccine project to identify high BARD1 expressing tumour cell lines had been completed and Stage 2 initiated to evaluate the in vivo effectiveness of BARD1 peptide vaccine formulations for reducing tumour growth in animal models, with the peptide vaccine results expected in late 2018.

Intellectual Property Portfolio

BARD1 LSL currently owns or licenses 5 patent families with 9 granted and 19 pending patent applications covering various BARD1 DNA and protein sequences, methods of diagnosis and treatment, and use in multiple cancers. During the year several patent cases were granted in 2 key patent families protecting the BARD1-Lung test in Australia, Japan and Israel, and the BARD1-Ovarian test in the USA.

On 28 July 2017, **Australian Patent number 2011292809** titled '*BARD1 isoforms in lung and colorectal cancer and use thereof*' was granted by IP Australia. This patent family protects the sequence of various BARD1 isoforms specific to lung and colorectal cancer, a method for detecting the presence of the specific BARD1 isoforms, and a method for treating and/or preventing lung cancer and colorectal cancer.

On 12 January 2018, **Divisional Japanese Patent number P6271636** titled '*BARD1 isoforms in lung and colorectal cancer and use thereof*' was granted by the Japan Patent Office. This patent covers modulators of specific BARD1 isoforms for use in treatment of lung or colorectal cancer.

On 1 March 2018, **Israeli Patent number 224766** titled '*BARD1 isoforms in lung and colorectal cancer and use thereof*' was granted by the Israeli Patent Office.

Corporate Update

On 20 July 2017, BARD1 announced that it had appointed international respiratory medicine expert, Dr Samuel Janes, as a member of its Advisory Board. Dr Janes provides independent scientific and clinical advice to guide the Company's research, development and business programs.

On 4 August 2017, the Company successfully completed a Placement to sophisticated investors followed by a Share Purchase Plan (SPP) to eligible shareholders of 189,165,811 shares at an issue price of \$0.008 to raise \$1.5 million (before costs).

On 22 March 2018, the Company successfully completed a Placement to sophisticated and professional investors of 86,666,666 shares at an issue price of \$0.015 to raise \$1.3 million (before costs). At 30 June 2018 the Company had 828,662,397 ordinary shares on issue.

On 20 June 2018, BARD1 announced that 446,506,472 securities held by the BARD1AG SA vendors were released from mandatory escrow comprising 229,503,236 Ordinary Shares and 217,003,236 Performance Shares that convert upon achievement of a future Milestone related to the successful completion of a 2000-subject clinical trial of BARD1-Lung that shows statistically significant evidence of equivalence, or superiority for detection of lung cancer with

greater than 80% sensitivity and 80% specificity, compared to the current gold standard Low Dose Computed Tomography (LDCT).

During the year, BARD1 progressed discussions on several corporate opportunities including mergers, acquisitions, in-licensing and other transactions to strengthen its business, expand its product pipeline, diversify its risk profile and grow long-term shareholder value.

Outlook

BARD1 is committed to realising the commercial potential of the BARD1 technology for detection and treatment of multiple cancers. With the excellent results achieved for BARD1-Ovarian this year, the Board of Directors intend to strengthen the Board with additional life sciences industry experienced directors, expand the management team to improve execution capability and secure access to Australian laboratory facilities to better position the company to advance its diagnostic and therapeutic projects towards key development milestones and grow shareholder value in financial year 2019.

In doing so, BARD1 is exploring a range of funding and corporate options and opportunities, with a guiding principle of minimising dilution and driving value for all shareholders.

Current research and development (R&D) activities are focused on the transfer of our research assay using Thermo Fisher's ProcartaPlex[®] Technology to Luminex[®] instrumentation that will enable further development and clinical validation of BARD1-Ovarian as a laboratory developed test for the Australian and US markets. The Company also intends to advance its BARD1-Lung program in 2019 and to expand applications for its BARD1 biomarker platform to early detection of other cancers.

SUBSEQUENT TO BALANCE DATE

On 10 July 2018, **US Patent number 10,018,639** titled '*Kits for detecting breast or ovarian cancer in body fluid sample and use thereof*' was granted by the United States Patent and Trademark Office (USPTO) The claims are directed to kits comprising peptides from BARD1 isoforms for detecting autoantibodies associated with breast or ovarian cancer.

At the date of this report, there are no subsequent events to 30 June 2018 other than that outlined above.

Consolidated Income Statement
For the year ended 30 June 2018

	Notes	for the year ended 30 June 2018 \$	for the 12 months ended 30 June 2017 \$
Revenue from ordinary activities		62,418	44,028
Research and development refund		210,785	-
Gain on disposal of held for trading assets		91,483	-
Depreciation expense		-	(8,008)
Employee benefits expense		(768,598)	(701,669)
Movement in fair value of investments held for trading assets		(127)	(8,990)
Impairment of available for sale financial assets		(28,230)	(56,458)
Foreign exchange gain/(loss)		(16,010)	13,754
Research and development		(770,842)	(1,089,976)
Patent expenses		(180,854)	(131,187)
Share based payment expense		(8,200)	(25,000)
Administration costs		(375,731)	(575,252)
Provision for Grant repayment		-	(65,413)
Loss before income tax		(1,783,906)	(2,604,171)
Income tax expense		-	-
Loss after income tax expense		(1,783,906)	(2,604,171)
Other comprehensive income Items that may be subsequently reclassified to operating result			
Foreign currency translation		(4,634)	3,187
Other comprehensive income/(loss) for the period		(4,634)	3,187
Total comprehensive loss for the period, net of tax		(1,788,540)	(2,600,984)

	for the year ended 30 June 2018 \$	for the 12 months ended 30 June 2017 \$
Earnings/(loss) per share		
Basic earnings/(loss) per share	(0.0026)	(0.0045) ⁽¹⁾
Diluted earnings/(loss) per share	(0.0026)	(0.0045) ⁽¹⁾

(1) The loss per share calculations for the period ended 30 June 2017 have been adjusted by factors of 1.041 and 1.008 respectively to reflect the bonus element of the capital raising and Share Purchase Plan completed subsequent to year end.

The EPS Calculation is based on a weighted average number of shares totalling 695,754,026 (ordinary shares) for the year ended 30 June 2018 (2017: 552,208,915 ordinary shares based on the issued capital of BARD1AG retrospectively adjusted for the merger ratio). As at 30 June 2018 the Company had 828,662,397 ordinary shares on issue.

Consolidated Statement of Financial Position

As at 30 June 2018

	Notes	as at 30 June 2018 \$	as at 30 June 2017 \$
Current assets			
Cash and cash equivalents	1	1,445,657	650,051
Receivables		3,465	31,956
Held for trading investments		32	16,659
Prepayment		3,983	-
Total current assets		1,453,137	698,666
Non-current assets			
Financial assets classified as available-for-sale		-	28,230
Total non-current assets		-	28,230
Total assets		1,453,137	726,896
Current liabilities			
Trade and other payables		238,212	422,946
Provisions		84,438	46,013
Total current liabilities		322,650	468,959
Total liabilities		322,650	468,959
Net assets		1,130,487	257,937
Equity			
Issued capital	3	9,298,385	6,645,495
Distribution reserve		(309,421)	(309,421)
Share based payment reserve		8,200	-
Foreign exchange translation reserve		(42,719)	(38,085)
Accumulated losses		(7,823,958)	(6,040,052)
Total equity		1,130,487	257,937
Net tangible assets per security		\$0.0014	\$0.0005

Consolidated Cash Flow Statement

For the year ended 30 June 2018

	Notes	for the year ended 30 June 2018 \$	for the year ended 30 June 2017 \$
Cash flows from operating activities			
Interest received		7,210	4,204
Other income		55,208	39,824
Payments to suppliers & employees		(2,238,470)	(2,422,341)
Research and development refund		210,785	-
Net cash flows used in operating activities		(1965,267)	(2,378,313)
Cash flows from investing activities			
Net cash received on sale of held for trading assets		107,983	-
Net cash flows from investing activities		107,983	-
Cash flows from financing activities			
Proceeds from issue of shares		2,813,326	-
Convertible notes repaid		-	(69,387)
Share issue costs		(160,436)	-
Net cash flows (used in)/from financing activities		2,652,890	(69,387)
Net increase/(decrease) in cash held		795,606	(2,447,700)
Cash and cash equivalents at beginning of period		650,051	3,097,751
Cash and cash equivalents at end of period	1	1,445,657	650,051

Consolidated Statement of Changes in Equity

For the year ended 30 June 2018 and for the year ended 30 June 2017

	Issued Capital \$	Foreign Currency Translation reserve \$	Distribution Reserve	Share Based Payments Reserve	Accumulated losses \$	Total equity \$
At 31 December 2017	6,620,495	(41,272)	(309,421)	-	(3,435,881)	2,833,921
Loss for the year	-	-	-	-	(2,604,171)	(2,604,171)
Share based payment	25,000	-	-	-	-	25,000
Other comprehensive income	-	3,187	-	-	-	3,187
At 30 June 2017	6,645,495	(38,085)	(309,421)	-	(6,040,052)	257,937
Issue of shares	2,652,890	-	-	-	-	2,652,890
Loss for the year	-	-	-	-	(1,783,906)	(1,783,906)
Share based payment	-	-	-	8,200	-	8,200
Other comprehensive income	-	(4,634)	-	-	-	(4,634)
At 30 June 2018	9,298,385	(42,719)	(309,421)	8,200	(7,823,958)	1,130,487

1. Reconciliation of cash

Reconciliation of cash at the end of the period (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows:	As at 30 June 2018 \$	As at 30 June 2017 \$
Cash at bank	1,445,657	650,051
Total cash at end of period	1,445,657	650,051

2. Dividends paid and proposed

No dividends have been paid or proposed during the year.

3. Issued capital

	as at 30 June 2018 \$	as at 30 June 2017 \$
Ordinary shares (net of issue costs)	9,298,385	6,645,495

	Number of shares	\$
At 30 June 2017	552,829,919	6,645,495
Issue of shares	275,832,478	2,652,890
At 30 June 2018	828,662,397	9,298,385

4. Group structure

Companies within the BARD1 Life Sciences Group (all wholly owned) carry out designated activities:

BARD1 Life Sciences limited – Holding Company
BARD1AG – development of the BARD1 Lung Cancer Test

5. Events subsequent to the balance date

On 10 July 2018, **US Patent number 10,018,639** titled '*Kits for detecting breast or ovarian cancer in body fluid sample and use thereof*' was granted by the United States Patent and Trademark Office (USPTO) The claims are directed to kits comprising peptides from BARD1 isoforms for detecting autoantibodies associated with breast or ovarian cancer.

At the date of this report, there are no subsequent events to 30 June 2018 other than that outlined above

6. Annual meeting

(Preliminary final report only)

The annual meeting will be held as follows:

Place	45 Ventnor Avenue, West Perth WA
Date	On or before 30 November 2018
Time	TBA
Approximate date the *annual report will be available	On or before 30 October 2018

Compliance statement

- 1 This report has been prepared in accordance with AASB Standards, other AASB authoritative pronouncements and Urgent Issues Group Consensus Views or other standards acceptable to ASX.
- 2 This report, and the +accounts upon which the report is based (if separate), use the same accounting policies.
- 3 This report does give a true and fair view of the matters disclosed.
- 4 This report is based on +accounts to which one of the following applies.
(Tick one)

<input type="checkbox"/>	The +accounts have been audited.	<input type="checkbox"/>	The +accounts have been subject to review.
<input checked="" type="checkbox"/>	The +accounts are in the process of being audited or subject to review	<input type="checkbox"/>	The +accounts have <i>not</i> yet been audited or reviewed.

Sign here: Date: 31 August 2018

Print name: Peter Gunzburg
 Chairman