

QUARTERLY BUSINESS UPDATE

Perth, Australia, 31 October 2018: BARD1 Life Sciences Limited (**BARD1 LSL** or the **Company**) (ASX:BD1), a biotechnology company developing non-invasive cancer diagnostics, today released its Appendix 4C and quarterly business update for the quarter to 30 September 2018.

- **Cash position of \$1.13m** as at 30/09/2018
- **Development of world-first BARD1-Breast Cancer Test:** BARD1-Breast cancer test shows high diagnostic accuracy for detection of breast cancer with 70% sensitivity and 88% specificity
- **Excellent accuracy of BARD1-Ovarian in high-risk women:** BARD1-Ovarian cancer test shows excellent diagnostic accuracy in high-risk women with family history of breast/ovarian cancer or carrying *BRCA1/2* mutations achieving 89% sensitivity and 97% specificity
- **New patents granted:** Patents were granted in two key patent families protecting the BARD1-Ovarian and BARD1-Breast cancer tests in the USA, and the BARD1-Lung cancer test in China.

Financial update

The closing cash balance at the end of the first quarter on 30/09/18 was \$1.13m. The net operating cash outflow for the quarter was \$304k, down from the previous quarter (4Q FY2018: \$531k) and comprising Research and Development (R&D) expenditure of \$32k on the BARD1 pipeline, patent expenses of \$30k, and staff, corporate and administration costs of \$242k.

Research and Development (R&D) update

BARD1's R&D activities focused on completing case-control studies for its BARD1-Ovarian and new BARD1-Breast cancer tests and providing technical support to the Thermo Fisher assay development program.

Breast Cancer Dx Program

During the quarter, BARD1 initiated the BC-001 study to develop and evaluate the accuracy of a new BARD1-Breast cancer test for detection of breast cancer.

On 23/10/2018 BARD1 announced the development of a world-first BARD1-Breast cancer test for early detection of breast cancer. The results of the BC-001 study demonstrated that the BARD1-Breast cancer test had high diagnostic accuracy for detection of breast cancer across common subtypes and all stages with AUC 0.86, 70% sensitivity and 88% specificity. The study was validated in an independent sample set of benign breast lesions that showed that the BARD1-Breast cancer test accurately distinguished malignant breast cancer from benign lesions.

The new BARD1-Breast cancer test uses the same BARD1 autoantibody test methodology and Luminex instrumentation as the BARD1-Ovarian cancer test enabling fast development and parallel clinical testing.

There is currently no blood test available for screening or early detection of breast cancer. Breast cancer currently has good 5-year survival of 90% due to mammography screening, increased awareness and better treatments, but not all women are eligible, can use or have access to mammograms.

BARD1 plans to develop BARD1-Breast as a screening test for early detection of breast cancer in average-risk asymptomatic women to detect cancer early, increase screening uptake, improve survival and reduce healthcare costs. Additionally, BARD1-Breast could be used as a diagnostic aid to assess the risk of malignancy following inconclusive mammography test results. This represents a key market opportunity for the company with the global breast cancer diagnostics market valued at US\$20.1b in 2013.

Ovarian Cancer Dx Program

The Assay Development program with Thermo Fisher Scientific to transfer the research assay to Luminex® instrumentation progressed during the quarter. The assay feasibility phase is underway for the BARD1-Ovarian test and assay development is expected to be completed in March 2019. The Company will update the market on the assay development program when appropriate.

On 06/09/2018 BARD1 announced positive results from its OC-R001 Study to evaluate and compare the accuracy of the improved BARD1-Ovarian test to detect ovarian cancer in high-risk women with a family history of breast/ovarian cancer or carrying BRCA1/2 mutations. The results demonstrated that BARD1-Ovarian showed outstanding diagnostic accuracy in high-risk women across all cancer stages of 0.97 AUC, 89% sensitivity and 97% specificity.

There is currently no screening test recommended for early detection of ovarian cancer in either average-risk or high-risk women. But, it is known that early detection of ovarian cancer saves women's lives by improving 5-year survival from an average of 47.4% to 92.3% if diagnosed early, compared with 29.2% when diagnosed late.

BARD1 plans to develop BARD1-Ovarian as a screening test for early detection of ovarian cancer in high-risk women with a family history of breast/ovarian cancer or carrying BRCA1/2 mutations. This represents a significant market opportunity with the global ovarian cancer diagnostics market valued at US\$7.2b in 2013.

Importantly, the combination of the BARD1-Breast and BARD1-Ovarian cancer tests provide an effective screening tool for early detection of breast/ovarian cancers in high-risk women with Hereditary Breast and Ovarian Cancer (HBOC) syndrome to detect cancer early, save women's lives and avoid unnecessary surgery.

Lung Cancer Dx Program

No new studies were conducted for BARD1-Lung during the quarter.

BARD1 plans to develop the BARD1-Lung cancer test as a screening test for early detection of lung cancer in high-risk asymptomatic individuals. The global lung cancer diagnostics market was valued at US\$26.0b in 2013.

Cancer Vaccine Program

The Cancer Vaccine collaboration with the Institute for Respiratory Health (IRH) to evaluate the *in vivo* effectiveness of BARD1 peptide vaccine formulations for triggering immune response and inhibiting tumour growth in animal models continued during the quarter, with the peptide vaccine results expected in December 2018.

Intellectual Property (IP) Portfolio update

On 12/07/2018 BARD1 announced that key US Patent No 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. This patent provides IP protection for the BARD1-Ovarian and BARD1-Breast cancer tests.

On 24/10/2018 BARD1 announced that Chinese Divisional Patent No 201610347489.9 titled "BARD1 isoforms in lung and colorectal cancer and use thereof" was granted by the China National Intellectual Property Administration (CNIPA). This patent provides additional coverage over the parent case for specific BARD1 isoforms, various methods and kits for use in the detection of the specific BARD1 isoforms, and methods for treatment or prevention of lung and colorectal cancer. This patent provides additional IP protection for the BARD1-Lung cancer test.

Corporate update

On 12/08/2018 Non-Executive Director Professor Geoffrey Laurent passed away suddenly whilst overseas. Geoff was a leading respiratory scientist and highly respected member of the BARD1 Board who made an invaluable contribution to the strategic direction of the Company since his appointment in 2016. BARD1 has not as yet appointed another Non-Executive Director.

During the quarter BARD1 continued to explore various corporate and fundraising opportunities to strengthen its business, expand its product pipeline, diversify its risk profile, and grow long-term shareholder value.

Outlook

BARD1 now has three BARD1 autoantibody tests in development for breast, ovarian and lung cancers. BARD1 is focused on the parallel development and commercialization of both its BARD1-Ovarian and new BARD1 Breast Cancer tests to take advantage of commercial synergies for early detection of breast/ovarian cancers in high-risk women with HBOC syndrome. The Company also intends to advance its BARD1-Lung program and to expand applications for its BARD1 tumour marker platform to early detection of other cancers.

Assay development is currently underway by our contract development partner Thermo Fisher Scientific to transfer the research assay to Luminex[®] instrumentation. Clinical studies are then expected to commence in 2019 for both BARD1-Breast and BARD1-Ovarian to evaluate clinical performance with expected launch as Laboratory Developed Tests (LDTs) by early 2021.

The Company's strategy is to complete clinical validation studies of its BARD1 tests and then commercialize its products through licensing the 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.

The new research results in breast cancer further validate the company's biomarker platform, ability to expand the diagnostic pipeline to other cancers with unmet needs and the commercial potential of BARD1's diagnostic assets to investors and partners. With these new breast cancer results, BARD1 will continue to advance discussions with its potential corporate and financial partners to build the Company and speed development and commercialisation of its diagnostic assets to maximize value for shareholders.

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ABOUT BARD1 LIFE SCIENCES LTD

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 BARD1 autoantibody tests in development for early detection of breast, ovarian and lung cancers. Additional diagnostic projects will be evaluated for other cancers. The company also has a cancer vaccine project at research-stage for treatment of cancer. BARD1 is committed to transforming the early detection of cancer to save lives. For more information on BARD1, see www.bard1.com.

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Name of entity

BARD1 LIFE SCIENCES LIMITED

ABN

58 009 070 384

Quarter ended ("current quarter")

30 SEPT 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	0	0
1.2 Payments for		
(a) research and development	(32)	(32)
(b) patent fees	(30)	(30)
(c) advertising and marketing	0	0
(d) leased assets	0	0
(e) staff costs	(125)	(125)
(f) administration and corporate costs	(118)	(118)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants and tax incentives	0	0
1.8 Other (ATO gst Refund)	0	0
1.9 Net cash from / (used in) operating activities	(304)	(304)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	0	0
(b) businesses (see item 10)	0	0
(c) investments	0	0
(d) intellectual property	0	0
(e) other non-current assets	0	0

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	0	0
	(b) businesses (see item 10)	0	0
	(c) investments	0	0
	(d) intellectual property	0	0
	(e) other non-current assets	0	0
2.3	Cash flows from loans to other entities	0	0
2.4	Dividends received (see note 3)	0	0
2.5	Other (provide details if material)	0	0
2.6	Net cash from / (used in) investing activities	0	0

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	0	0
3.2	Proceeds from issue of convertible notes	0	0
3.3	Proceeds from exercise of share options	0	0
3.4	Transaction costs related to issues of shares, convertible notes or options	0	0
3.5	Proceeds from borrowings	0	0
3.6	Repayment of borrowings	0	0
3.7	Transaction costs related to loans and borrowings	0	0
3.8	Dividends paid	0	0
3.9	R&D Development Grants		
3.10	Net cash from / (used in) financing activities	0	0

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	1,434	1,434
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(304)	(304)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		
4.4	Net cash from capital raising (item 3.10 above)	0	0
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	1,130	1,130

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	1,130	1,434
5.2	Call deposits	0	0
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,130	1,434

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	60
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	0
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

Appendix 4C
Quarterly report for entities subject to Listing Rule 4.7B

7. Payments to related entities of the entity and their associates

**Current quarter
\$A'000**

7.1 Aggregate amount of payments to these parties included in item 1.2

0

7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3

0

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

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8. Financing facilities available

Add notes as necessary for an understanding of the position

**Total facility
amount at quarter
end
\$A'000**

**Amount drawn at
quarter end
\$A'000**

8.1 Loan facilities

0

0

8.2 Credit standby arrangements

0

0

8.3 Other (please specify)

0

0

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

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9. Estimated cash outflows for next quarter

\$A'000

9.1 Research and development

100

9.2 Product manufacturing and operating costs

0

9.3 Advertising and marketing

0

9.4 Leased assets

0

9.5 Staff costs

160

9.6 Administration and corporate costs

150

9.7 Other (provide details if material)

0

9.8 Total estimated cash outflows

410

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here: Company Secretary

Date: 31 October 2018

Print name: P Collinson

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.