

# **QUARTERLY BUSINESS UPDATE**

**Perth, Australia, 31 July 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 fourth quarter to 30 June 2018.

- Cash position of \$1.434M and RDTI refund received of \$211K
- Transfer of BARD1 assay to Luminex® platform: BARD1 signs Assay Development Agreement with Thermo Fisher Scientific to develop RUO BARD1 autoantibody assay using ProcartaPlex® Technology for performance on Luminex® instrumentation
- Improvement of BARD1-Ovarian test: BARD1-Ovarian test significantly improved by addition of the CA125 biomarker to the BARD1 algorithm achieving 88% sensitivity and 93% specificity in test sets

# **Financial update**

The closing cash balance at the end of the fourth quarter on 30/6/18 was \$1.434M. BARD1 received a Research and Development Tax Incentive (RDTI) refund of \$211K including \$94.9K for the 2016 financial year and \$115.8K for the 2017 financial year. The net operating cash outflow for the quarter was \$531K, up from the previous quarter (3Q FY2018: \$470K) and comprising Research and Development (R&D) expenditure of \$426K on the BARD1 pipeline, patent costs of \$48K, and staff, corporate and administration costs of \$270K.

# Research and Development (R&D) update

BARD1's R&D activities continued to focus on further case-control studies to optimise the panel and algorithm for BARD1-Ovarian for detection of ovarian cancer and the transfer its research assay to the Luminex® platform.

On 18/5/18 BARD1 announced that it had signed an Assay Development agreement with Thermo Fisher Scientific to transfer its current 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. The Assay Development project commenced in May-18 and is expected to take approximately nine months to complete.

#### **Ovarian Cancer Dx Program**

On 19/6/18 BARD1 announced that it had completed the 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.

BARD1 plans to develop BARD1-Ovarian as an accurate and reliable screening test for early detection of ovarian cancer when it can be potentially cured and help save women's lives. Upon successful completion of the Assay Development project to transfer the research BARD1 assay to the ProcartaPlex® Technology, BARD1 intends to conduct clinical studies in 2019 to evaluate the clinical performance of BARD1-Ovarian for early detection of ovarian cancer.

### **Lung Cancer Dx Program**

BARD1 plans to develop BARD1-Lung as an accurate and reliable screening test for early detection of lung cancer. Upon successful transfer of BARD1-Ovarian to the Luminex® platform, BARD1 intends to

undertake further case-control studies to optimise the BARD1-Lung panel and algorithm for early detection of lung cancer using the new multiplex BARD1 assay, then accelerate BARD1-Lung through the Assay Development-phase to develop and analytically validate the refined BARD1-Lung on Luminex® instrumentation in 2019 before advancing towards clinical studies.

# **Cancer Vaccine Program**

Stage 2 of the Cancer Vaccine collaboration with the Institute for Respiratory Health (IRH) to evaluate the *in vivo* effectiveness of BARD1 peptide vaccine formulations for reducing tumour growth in animal models continued during the quarter, with the peptide vaccine results expected in late 2018.

# **Intellectual Property Portfolio update**

On 12/7/18 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) on 10 July 2018. The issued United States claims are directed to kits comprising peptides from BARD1 isoforms for detecting autoantibodies associated with breast or ovarian cancer. Importantly, this patent provides protection for the BARD1-Ovarian test and any future breast cancer diagnostic test, with the European case currently under examination.

## **Corporate update**

On 20/6/18 BARD1 announced that 446,506,472 securities that were issued to 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 quarter BARD1 progressed discussions on several strategic business opportunities including business combination, acquisition, in-licensing, and other transactions to strengthen its business, expand its product pipeline, diversify its risk profile, and grow long-term shareholder value.

#### **Outlook**

The Company is pleased with the progress and excellent results for its BARD1-Ovarian test and is currently focused on the transfer of its current research assay using Thermo Fisher's ProcartaPlex® Technology for performance on Luminex® instrumentation that will enable further development and clinical validation 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.

- ENDS -

### FOR MORE INFORMATION PLEASE CONTACT:

Peter Gunzburg Dr Leearne Hinch

Chairman CEO

E <u>peter@bard1.com</u>

M +61 400 414 416

## **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 development pipeline includes two BARD1 autoantibody tests in development for early detection of lung and ovarian cancers, and a cancer vaccine project at research-stage for treatment of cancer. Additional diagnostic projects are being evaluated for prostate, breast and other cancers. BARD1 is committed to transforming the early detection and prevention of cancer to help improve patients' lives. For more information on BARD1, see <a href="https://www.bard1.com">www.bard1.com</a>.

Rule 4.7B

# **Appendix 4C**

# **Quarterly report for entities subject to Listing Rule 4.7B**

# Name of entity

BARD1 LIFE SCIENCES LIMITED	
ABN Quarter ended ("current quarter")	
58 009 070 384	30 JUNE 2018

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	0	0
1.2	Payments for		
	(a) research and development	(426)	(1,008)
	(b) patent fees	(48)	(210)
	(c) advertising and marketing	0	0
	(d) leased assets	0	0
	(e) staff costs	(194)	(601)
	(f) administration and corporate costs	(76)	(413)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	2	7
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	211	211
1.8	Other (ATO gst Refund)	0	53
1.9	Net cash from / (used in) operating activities	(531)	(1,961)

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	108
	(d) intellectual property	0	0
	(e) other non-current assets	0	0

<sup>+</sup> See chapter 19 for defined terms.

01/09/2016

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 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	108

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	0	2,813
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	(71)	(169)
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	(71)	2,644

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	2,036	645
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(531)	(1,961)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		108
4.4	Net cash from capital raising (item 3.10 above)	(71)	2,644
4.5	Effect of movement in exchange rates on cash held		(2)
4.6	Cash and cash equivalents at end of quarter	1,434	1,434

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	1,434	2,036
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)	1,434	2,036

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 transactitems 6.1 and 6.2	tions included in

<sup>+</sup> See chapter 19 for defined terms. 01/09/2016

Appendix 4C Page 3

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 trans	sactions included in

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

8.	Financing facilities available Add notes as necessary for an understanding of the position
8.1	Loan facilities
8.2	Credit standby arrangements
8.3	Other (please specify)

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
0	0
0	0
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.

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	150
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	180
9.7	Other (provide details if material)	0
9.8	Total estimated cash outflows	490

01/09/2016

<sup>+</sup> See chapter 19 for defined terms. Appendix 4C Page 4

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 JULY 2018

Print name: P Collinson

# **Notes**

- 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.

<sup>+</sup> See chapter 19 for defined terms. 01/09/2016