

QUARTERLY BUSINESS UPDATE

- **Strong commercial progress:**
 - Achieved hTERT registration in South Korea and first order of \$80,000
 - RUO¹ EXO-NET™ product on-track for commercial launch in Q2 CY2021
 - Advanced discussions with potential partners for the commercialisation of BARD1's diagnostic pipeline
- **Significant progress across all R&D programs:**
 - Positive results from independent evaluation of BARD1 autoantibody assay at Griffith University (post quarter-end)
 - Released excellent initial SubB2M-based SPR² assay results for detecting ovarian and breast cancers
 - Progressed initial feasibility studies to develop a SubB2M-based ELLBA³ for monitoring of ovarian and breast cancers
 - Progressed initial feasibility studies to develop SubB2M-based ELISAs⁴ for prostate and pancreatic cancers
 - Positive results from EXO-NET™ evaluation in pancreatic cancer
 - Signed license option agreement for a new type 3c diabetes test (post quarter-end)
- **New patents granted:**
 - US patent granted for NETs technology covering EXO-NET™ product
 - Australian patent granted covering hTERT assay
- **Cash position:** Cash balance of \$6.0m as at 31 March 2021

Melbourne, Australia, 30 April 2021: BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**), a diagnostics company developing non-invasive cancer diagnostics, today released its Appendix 4C and Quarterly Business Update for the quarter ended 31 March 2021.

COMMERCIALISATION UPDATE

BARD1 made strong progress in the March quarter for its sales, business development and commercialisation activities related to its hTERT product, RUO EXO-NET™ product and cancer diagnostics pipeline.

hTERT business

Revenue from the Company's 'in-market' product hTERT continued to be impacted by the reduction in routine pathology due to COVID-19. Recently however there has been some recovery in demand which, combined with BARD1's previously announced strategy to focus on high-volume customers in the USA, should provide a lift in hTERT revenues in FY2022.

On 12 March 2021, BARD1 announced it had received Class II IVD registration for hTERT from South Korea's Ministry of Food and Drug Safety. This approval was an important step in launching hTERT in the South Korean market. It also triggered a commitment from the Company's exclusive distributor, Mirax Corporation, to place an initial purchase for A\$80,000. BARD1's technical support team are working with Mirax to initiate a number of evaluations at key reference centres in South Korea. The launch of hTERT in South Korea was supported by a presentation given to the 2021 Korean Society of Cytopathology by Dr Ryoo, Assistant Professor at Seoul National University Hospital.



Figure 1: New hTERT packaging

¹ Research Use Only (RUO)

² Surface Plasmon Resonance (SPR)

³ Enzyme Linked Ligand Binding Assay (ELLBA)

⁴ Enzyme Linked Immunosorbent Assay (ELISA)

Additionally, the European rollout of hTERT is progressing with evaluations of hTERT at multiple reference centres in Sweden, Greece and Israel.

BARD1's US-based hTERT Commercial Manager, Michael Gunderson, who is a registered histotechnologist with over 20 years' experience in the field, presented the use of hTERT as an adjunct biomarker for the investigation of bladder cancer at the Texas State Histology Meeting in Austin, Texas USA. Michael received "The Robert A. Clark Memorial Grant" award for his presentation.

EXO-NET™ commercialisation

BARD1's EXO-NET™ product is a next generation exosome isolation and purification technology. During the quarter, BARD1 accelerated the commercial development of the Company's RUO EXO-NET™ product towards its planned commercial launch for sale to academia, research institutions and biopharma in 2Q CY2021.

Initial commercialisation of EXO-NET™ as a research tool has the potential to embed the technology into the discovery, research and development phases for multiple diagnostics and therapeutic applications. Importantly, this may lead to future licensing agreements for development and commercialisation of exosome-based products incorporating BARD1's proprietary Molecular NET technology.

In-house production of EXO-NET™ at BARD1's US facility is underway with initial production lots completed in preparation for the 2Q CY2021 launch.

Key promotional activities to support the RUO EXO-NET launch are either completed or underway, including establishment of a dedicated EXO-NET website (see www.exo-net.com), scientific poster, EXO-NET™ animation and Key Opinion Leader video.

BARD1 has established multiple collaborations with leading research institutes to evaluate the RUO EXO-NET™ product to validate potential customer interest and use in research applications. Initial feedback from researchers has supported its multiple advantages over existing exosome isolation technologies and is expected to result in future publications supporting the use of EXO-NET™ in various exosome research applications.

BARD1 also progressed discussions with several multinational companies supplying exosome capture and diagnostic tools to introduce the parties to RUO EXO-NET's unique features and benefits for exosome research. EXO-NET™ advantages include its fast, accurate and efficient capture and isolation of exosomes from any biological sample including plasma, saliva, urine and cell culture supernatants in less than 30 minutes at high purity.

Diagnostics pipeline commercialisation

The multi-product BARD1 diagnostics pipeline includes blood tests in development for breast, ovarian, prostate, and pancreatic cancers based on our BARD1 autoantibody, SubB2M and EXO-NET™ technologies. These cancer applications represent large global market opportunities in areas of important unmet medical needs for early detection and monitoring of cancer.

To support the commercialisation of the Company's diagnostics programs, BARD1 continues to progress early-stage discussions with multiple potential laboratory partners who could establish the BARD1 pipeline diagnostics as LDTs⁵ in the US. The Company also continues to engage with Payors and Insurers in the US to determine their clinical data requirements for future reimbursement of our diagnostic tests. The commercialisation strategy for BARD1's diagnostics pipeline is to first launch the tests as LDTs, followed by an FDA⁶ IVD⁷ submission and clinical studies to support 510k clearance⁸ or PMA⁹ approval.



Figure 2: EXO-NET™ packaging

⁵ Laboratory Developed Tests (LDTs)

⁶ Food and Drug Administration (FDA)

⁷ In Vitro Diagnostic (IVD)

⁸ PreMarket Notification (510k)

⁹ PreMarket Approval (PMA)

RESEARCH AND DEVELOPMENT (R&D) UPDATE

The Company made significant progress across our BARD1 autoantibody (AAb), SubB2M, NETs and hTERT programs during the March quarter. The R&D programs target areas of significant unmet needs with a focus on early cancer detection. Our technologies have the potential to deliver significant commercial and clinical benefits to patients, the healthcare system and our shareholders.

BARD1 autoantibody program

Griffith University's Mucosal Immunology Research Group (MIRG) was contracted to evaluate the RUO BARD1 kit alone and in combination with CA125 for detection of ovarian cancer in 241 samples. The study was completed in the March quarter, the data analysed by an independent statistician and the results announced on 29 April 2021.

The results showed that using two BARD1 peptides in combination with CA125 levels less than 70 Units/ml provided a sensitivity of 91% and specificity of 50% for detection of ovarian cancer, compared to 27% sensitivity for CA125 alone in this sample group. The high level of sensitivity obtained by combining the BARD1 peptides with CA125 is encouraging for the potential use of this assay for early detection of ovarian cancer in high-risk women with Hereditary Breast and Ovarian Cancer syndrome (HBOC), where high sensitivity is important.

SubB2M program

SubB2M is a pan-cancer probe developed by researchers at the University of Adelaide and Griffith University designed to specifically bind to Neu5Gc, a sugar found specifically on cancers and cancer-associated biomolecules. BARD1 has an exclusive worldwide license to develop and commercialise SubB2M for cancer diagnostic applications.

On 11 February 2021, BARD1 announced excellent results released at the Australia New Zealand Gynaecological Oncology Group Conference 2021 from a Griffith University study using a SubB2M-based SPR¹⁰ showing 100% specificity and 100% sensitivity for detection of all stages of ovarian cancer.

On 15 February 2021, BARD1 announced additional excellent results released at the Lorne Cancer Conference 2021 from a Griffith University study using a SubB2M-based SPR assay showing 100% specificity and over 95% sensitivity for detection of all stages of breast cancer.

BARD1 has executed a 2-year collaborative research agreement with Griffith University to develop SubB2M-based ELISAs¹¹ for monitoring and detection of breast and ovarian cancers. Initial feasibility studies to transfer the test from an SPR to an ELISA platform progressed during the period.

In addition, BARD1 commenced its own in-house ELISA development program using SubB2M for detection of prostate and pancreatic cancers. Following a successful ethics committee application, samples from patients with prostate and pancreatic cancer were obtained from the Victorian Cancer Biobank. Initial feasibility studies were commenced to develop ELISAs for both these cancers combining SubB2M and antibodies to tissue specific biomarkers from existing commercial blood tests. Importantly, the SubB2M technology could enable the development and commercialisation of fast-to-market, next-generation tests with the potential to revolutionise cancer detection and monitoring for multiple cancers including breast, ovarian, prostate, and pancreatic cancers.

BARD1 researchers also commenced studies using SubB2M to improve cancer detection in immunohistochemistry (IHC) tissue sections. Given SubB2M's exquisite specificity for cancer, and BARD1's existing experience in immunohistochemistry and immunocytochemistry (through the hTERT program), SubB2M has been used in initial feasibility experiments to determine its ability to discriminate areas of cancer from non-cancer in tissue sections using a modified automated IHC protocol. Early results are encouraging, and the Company aims to expand this work in the next quarter across multiple potential clinical applications.

¹⁰ Surface Plasmon Resonance (SPR)

¹¹ Enzyme-linked immunosorbent assay (ELISA)

NETs program

During the quarter, EXO-NET™ prototypes were supplied to researchers at the University of Sydney and University of Queensland for evaluation in studies on cancer-derived exosomes, with positive results to date. Additionally, in house studies comparing EXO-NET™ with competitor technologies have demonstrated superior performance of EXO-NET™ over the competitors, and this data is being incorporated into promotional material to support the launch and marketing of the RUO EXO-NET™ product.

BARD1 also progressed development of customised EXO-NETs for use in the manufacturing of exosomes for therapeutic applications. BARD1 is in discussion with two Australian-based companies working in the therapeutic exosome field to assess appropriate applications for customised EXO-NETs in the exosome manufacturing process.

On 16 March 2021, BARD1 announced positive results from its collaboration with Minomic International to evaluate BARD1's EXO-NET™ for capture of exosomes and Minomic's anti-GPC-1 antibody for detection of pancreatic cancer. The results showed that BARD1's EXO-NET efficiently isolated exosomes from pancreatic cancer patients and healthy control plasma samples, and Minomic's GPC-1 antibody could specifically bind EXO-NET™ isolated pancreatic cancer exosomes and not bind healthy (non-cancer) exosomes. This pilot study indicated the scientific feasibility of utilising EXO-NET™ to isolate exosomes for pancreatic cancer detection in conjunction with an anti-GPC-1 antibody. Importantly, this work could lead to the development of a customized GPC-1-EXO-NET™ test for the early detection of pancreatic cancer to improve patient outcomes and survival for this important unmet need. Notably, the University of Liverpool's assay for type 3c diabetes could be used to identify people at high-risk for pancreatic cancer.

hTERT study

The Company has completed the evaluation of clinical immunocytochemical specimens aimed at assessing the efficacy of an alternative scoring algorithm for the interpretation of cancer status. This could simplify laboratory implementation and speed customer conversion. A final report of the analysis is expected by June 2021.

Option Agreement with University of Liverpool for T3cDM

After quarter end on 13 April 2021, BARD1 announced it had signed a license option agreement with the University of Liverpool for two novel protein markers for the development and commercialisation of a novel type 3c diabetes (T3cDM) blood test based on adiponectin and interleukin-1 receptor antagonist (IL-1Ra). A blood test for T3cDM could be an important diagnostic assay to distinguish T3cDM from T2DM in individuals diagnosed with new-onset diabetes, and there would also be a strong clinical case for using it to screen all individuals diagnosed with T3cDM for pancreatic cancer. Individuals that test positive for T3cDM could be placed in an enhanced surveillance program and screened annually for pancreatic cancer using BARD1's specific pancreatic cancer test/s currently in development. Importantly, this approach could provide a significant improvement in outcomes for patients with both T3cDM and pancreatic cancer.

INTELLECTUAL PROPERTY (IP) PORTFOLIO UPDATE

Australian Patent 2015218188 entitled 'Method of Detecting Cancer' was granted by IP Australia on 18 February 2021. This patent covers the use of the Company's hTERT antibody to resolve inconclusive cytology and detect malignant cells.

US patent 10,900,962 entitled 'Molecular nets and devices for capturing analytes including exosomes' was granted by the United States Patent and Trademark Office (USPTO) on 26 January 2021. This patent covers BARD1's unique Molecular Net technology including BARD1's antibody-based EXO-NET™ product designed for the capture of exosomes.

QUALITY AND REGULATORY UPDATE

BARD1's hTERT product is registered in the US, Europe, Australia, and South Korea. Registration relies on a strong Quality Management System, based on ISO 13485:2016. In line with global changes to the medical device regulatory landscape, BARD1 is transitioning to comply with:

- the new European IVDR (In Vitro Diagnostic Regulation);

- Global UDI (Unique Device Identification barcodes for device traceability); and
- State-of-the-art Risk Management principles (ISO14971:2019).

To support these substantial regulatory improvements and, driven by the increased product portfolio and technical sophistication of the business, BARD1 is implementing a cloud-based eQMS solution (electronic Quality Management System).

CORPORATE UPDATE

On 15 January 2021, BARD1 announced that Dr Irminger-Finger stepped-down from the BARD1 Life Sciences Ltd board of directors.

On 24 February 2021, BARD1 announced that Tony Walker and former director and Founding Scientist of the Company, Dr Irminger-Finger, had commenced legal proceedings against the Company in the Supreme Court of Victoria. BARD1 advised that it would defend the proceedings and file a comprehensive defence.

FINANCIAL UPDATE

BARD1's cash balance at 31 March 2021 was approximately \$6.0m. Operating cash receipts during the quarter included:

- \$42k from the sale of hTERT product (year to date \$271k);
- \$100k from the first tranche of the Export Market Development Grant (EMDG) for the 2020 financial year;
- \$11k from the Biomedical Translation Bridge (BTB) grant program supporting the development of SubB2M-based liquid biopsy tests to detect and monitor breast cancer (the first payment received from the grant);
- \$7k from the Federal government's Jobkeeper program; and
- \$8k in bank interest.

Net cash used in operating activities for the quarter was \$1,488k with the key contributors being:

- Research and Development (R&D) expenditure of \$816k (year to date - \$2,006k) to support the development of the projects discussed under 'Research & Development (R&D) Update' above;
- Non-R&D staff costs of \$477k (year to date \$1,360k);
- Administration and corporate costs of \$261k (year to date \$1,078k); and
- Patent fees of \$58k (year to date \$310k).

During the quarter a total of \$286k in new capital was received by the Company as a result of the exercise of share options. The exercise of these options resulted in the issue of 238,943 new ordinary shares.

Payments to related parties of \$63k per section 6.1 of the Appendix 4C are for director fees and costs. A total of \$145k was reported for the prior quarter. The prior quarter included payments made to Dr Irmgard Irminger-Finger who resigned from the Board in January 2021.

Further details are provided in the Appendix 4C attached.

Authorised by the Company Secretary, Tony Di Pietro.

ENDS

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ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd is a leading Australian diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on developing and commercialising best-in-class diagnostic solutions based on its BARD1, SubB2M, Molecular NETs and hTERT platforms for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology testing and development-stage tests for ovarian, breast, lung, prostate and pancreatic cancers. The Company is also commercialising its Molecular NETs platform for sample preparation and is launching its proprietary EXO-NET™ exosome capture tool for use in research for exosome-based diagnostics and therapeutics. For further information see www.bard1.com.

FORWARD LOOKING STATEMENTS

This announcement contains certain 'forward-looking statements' within the meaning of the securities laws of applicable jurisdictions. Forward-looking statements can generally be identified by the use of forward-looking words such as 'may,' 'should,' 'expect,' 'anticipate,' 'estimate,' 'scheduled' or 'continue' or the negative version of them or comparable terminology. Any forecasts or other forward-looking statements contained in this announcement are subject to known and unknown risks and uncertainties and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There are usually differences between forecast and actual results because events and actual circumstances frequently do not occur as forecast and these differences may be material. The Company does not give any representation, assurance or guarantee that the occurrence of the events expressed or implied in any forward-looking statements in this announcement will actually occur and you are cautioned not to place undue reliance on forward-looking statements.

Appendix 4C

Quarterly cash flow 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")

31 MARCH 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	42	271
1.2 Payments for		
(a) research and development (<i>including allocated staff costs</i>)	(816)	(2,006)
(b) patent fees	(58)	(310)
(c) advertising and marketing	(24)	(79)
(d) product manufacturing and operating costs	(20)	(71)
(e) staff costs (<i>other than R&D staff</i>)	(477)	(1,360)
(f) administration and corporate costs	(261)	(1,078)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	8	38
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	100	100
1.8 Other (<i>Govt stimulus & BTB Grant</i>)	18	167
1.9 Net cash from / (used in) operating activities	(1,488)	(4,328)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(43)	(388)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (<i>Merger transaction costs</i>)	-	(645)
	Other (Sienna Cancer Diagnostics Cash Balance)	-	3,766
2.6	Net cash from / (used in) investing activities	(43)	2,733

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	286	286
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	286	286

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,258	7,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,488)	(4,328)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(43)	2,733
4.4	Net cash from capital raising (item 3.10 above)	286	286
4.5	Effect of movement in exchange rates on cash held	-	3
4.6	Cash and cash equivalents at end of period	6,013	6,013

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	1,992	787
5.2	Call deposits	4,021	6,471
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	6,013	7,258

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

63

-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	20	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 **Unused financing facilities available at quarter end** 20

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

Relates to the corporate credit card facility with the National Australia Bank.

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,488)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	6,013
8.3 Unused finance facilities available at quarter end (Item 7.5)	20
8.4 Total available funding (Item 8.2 + Item 8.3)	6,033
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	4

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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.

Date: 30 April 2021

Authorised by: By the Board of Directors

Authorised for release by Company Secretary – Tony Di Pietro
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.