

## QUARTERLY BUSINESS UPDATE

- **Strong commercial progress:**
  - hTERT receipts of \$184k for the period compared to previous quarter of \$42k
  - RUO<sup>1</sup> EXO-NET® launched and exosome capture data presented at ISEV2021 in May 2021
  - Multiple evaluations and partnering discussions underway for diagnostic pipeline
- **Significant R&D progress:**
  - Progressed feasibility studies to develop SubB2M blood tests for breast and ovarian cancers
  - New SubB2M breast cancer test manuscript submitted for publication
  - Feasibility demonstrated for a SubB2M IHC test in tissue biopsies
  - Results for BARD1 autoantibody assay on Luminex platform
  - Publication of BARD1 autoantibody test results for ovarian cancer on MSD platform
  - Signed license option agreement for new type 3c diabetes test
- **Strengthened IP portfolio:**
  - Two new patent applications filed protecting SubB2M and EXO-NET
  - Two new patents granted covering the BARD1 autoantibody tests in the US and South Korea
- **Corporate initiatives:**
  - Placement of \$15m at \$1.55 per share to institutional, sophisticated and professional investors including 1 option for every 2 shares purchased (post-quarter end)
  - SPP of \$2m announced including 1 option for every 2 shares purchased (post-quarter end)
- **Cash position:**
  - R&D Tax refund of \$644k received for FY20
  - Cash balance of \$5.0m as at 30 June 2021

**Melbourne, Australia, 30 July 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 30 June 2021.

### COMMERCIALISATION UPDATE

BARD1 advanced its sales, business development and commercialisation activities during the June quarter for its hTERT product, RUO EXO-NET product and cancer diagnostics pipeline.

#### hTERT business

The Company has seen a strong uplift in demand for the hTERT ICC test during the June quarter compared with the 2020 June quarter. hTERT revenues for financial year 2021 were increased by almost 30% compared to FY2020, underpinned by a post Covid-19 recovery in the “routine” pathology market in the USA, and the successful onboarding of new laboratories in the US and our South Korean distributor.

BARD1 is working with its distributors to advance the rollout of hTERT ICC in Europe. Multiple sites in Greece, Sweden and Israel have completed evaluations and are moving toward validation, which upon completion is expected to lead to initial sales in these countries.

#### EXO-NET® commercialisation

BARD1’s EXO-NET product is a next generation exosome isolation and purification technology. There is increasing research evaluating exosomes for both diagnostic and therapeutic applications. BARD1’s commercialisation strategy for EXO-NET is to embed the technology into the discovery, research and development phases for multiple diagnostic and therapeutic applications. This could lead to future

---

<sup>1</sup> Research Use Only (RUO)

licensing agreements for development and commercialisation of exosome-based products incorporating EXO-NET.

BARD1 launched EXO-NET at the International Society for Extracellular Vesicles (ISEV) in May. The conference was held as a virtual meeting in the USA with over 700 delegates attending from all over the world. In addition to sponsoring an exhibit at the conference, BARD1's US-based R&D Manager and inventor of EXO-NET, Dr Emily Stein, presented a poster titled "*EXO-NET, A Novel, Scalable Exosome Isolation Technology*". A copy of the poster and more details on EXO-NET can be found at [www.exo-net.com](http://www.exo-net.com).



Figure 1: EXO-NET Virtual Exhibit at ISEV

In November, BARD1 will be a platinum sponsor of the Australia & New Zealand Society for Extracellular Vesicles (ANZSEV) being held on the Gold Coast in Queensland. BARD1 will be conducting a "Wet Work Shop" and presenting a number of abstracts at this meeting.

BARD1 continues to progress collaborations with leading research institutes and other parties, in Australia and overseas, to evaluate the RUO EXO-NET product. Feedback from researchers strongly supports EXO-NET's speed, purity and yield advantages over existing exosome isolation technologies and is expected to result in future publications using EXO-NET in various exosome research applications.

### Diagnostics pipeline commercialisation

To support the commercialisation of the Company's diagnostic pipeline, BARD1 has initiated the development of Budget Impact Models to demonstrate a potential health economic advantage of implementing SubB2M-based breast and ovarian cancer tests in a clinical setting. These models will enable early engagement with US Payors and Insurers, as a first step in obtaining reimbursement.

## RESEARCH AND DEVELOPMENT (R&D) UPDATE

The Company progressed its SubB2M, NETs, BARD1 autoantibody (AAb), and hTERT programs during the June quarter. Our R&D programs target unmet needs for early detection of breast, ovarian, prostate and pancreatic cancers. Our technologies have the potential to deliver significant commercial and clinical benefits to patients, the healthcare system, and our shareholders.

### SubB2M program

SubB2M is an engineered protein that specifically binds to a sugar, Neu5Gc, found in human cancers tissues, cells and secretions. BARD1 has an exclusive worldwide license to develop and commercialise SubB2M for cancer diagnostic applications from the University of Adelaide and Griffith University.

BARD1 has a collaborative research agreement with Griffith University to develop SubB2M-based ELISAs<sup>2</sup> for monitoring and detection of breast and ovarian cancers. The breast cancer work is supported by a BTB Grant from MTP Connect. During the quarter, progress was made on defining the optimal components and construction of the ELISAs in breast and ovarian cancers.

On 25 June 2021, BARD1 announced that a SubB2M Breast Cancer Test manuscript had been submitted by researchers at Griffith University and the University of Adelaide to an international peer reviewed journal and was available as a pre-print online at <https://doi.org/10.1101/2021.06.21.449179>. The study showed that SubB2M can be used to detect all stages of breast cancer from blood samples with 100% specificity and over 95% sensitivity over healthy controls. The manuscript describes the method used for the SubB2M-based surface plasmon resonance (SPR) assays for both breast and ovarian cancer detection (100% sensitivity and specificity for all stages of ovarian cancer), the results for breast cancer and conclusions for the potential widespread commercial use of SubB2M-based blood tests for the early detection and monitoring of breast and ovarian cancers.

<sup>2</sup> Enzyme-linked immunosorbent assay (ELISA)

BARD1 progressed its in-house ELISA development program at its Melbourne laboratories using SubB2M for detection of prostate and pancreatic cancers.

On 25 May 2021, BARD1 announced feasibility of a SubB2M-based immunohistochemistry test for detection of breast cancer in tissue biopsy specimens. This demonstrates that SubB2M can be used in solid biopsy analysis of tumours as well as in serum testing, expanding the potential use of SubB2M across the discipline of pathology.

### **NETs program**

During the quarter, EXO-NET prototypes were supplied to researchers in Australia and internationally, following the launch promotion at the ISEV2021 Conference. Evaluations at the University of Sydney and University of Queensland (UQ) continued to demonstrate the value of EXO-NET for various exosome applications. Professor Carlos Salomon discussed his evaluation of EXO-NET in his exosome-based ovarian cancer research at UQ in the EXO-NET launch video, supporting its efficacy and value for high throughput sample processing. Additionally, further in-house studies comparing EXO-NET with competitor technologies have continued to demonstrate superior performance of EXO-NET over the competitors, and this data is being prepared for publication.

BARD1 also progressed development of customised EXO-NETs for use in the manufacturing of exosomes for therapeutic applications. Discussions were advanced with an Australian therapeutic exosome company to supply the modified EXO-NET prototype for evaluation in their proprietary therapeutic exosome manufacturing process.

### **BARD1 autoantibody program**

On 29 April 2021, BARD1 announced results from its independent evaluation by Griffith University's Mucosal Immunology Research Group (MIRG) of the RUO BARD1 kit alone and in combination with CA125 for detection of 241 new and previously tested ovarian cancer samples on Luminex instrumentation.

The results showed that there were three (3) consistent BARD1 peptides that were best able to discriminate ovarian cancer from healthy controls, but not with sufficient discriminatory accuracy alone. Additionally, 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. However, these results show that further analysis of the BARD1 autoantibody test is required to determine the future development path and commercial potential of this test. The Company is also actively investigating using BARD1 isoform mRNA analysis in liquid biopsies as an alternative to autoantibodies for early cancer detection.

On 29 June 2021, BARD1 announced autoantibody test results for ovarian cancer were published in the peer-reviewed journal Genes titled "BARD1 Autoantibody Blood Test for Early Detection of Ovarian Cancer". The paper reported data from previously announced studies performed at the University of Geneva in 2018. The authors concluded that "measurement of autoantibody binding to a number of BARD1 epitopes combined with CA125 could distinguish OC from healthy controls with high accuracy. This BARD1-CA125 test was more accurate than measurements of BARD1 autoantibody or CA125 alone for all OC stages and menopausal status." The paper concluded that further data was required to confirm the potential of the test for ovarian cancer screening.

### **hTERT study**

The Company completed an internal evaluation of clinical immunocytochemical specimens aimed at assessing the efficacy of an alternative scoring algorithm for the interpretation of cancer status, with promising results. This is expected to simplify laboratory implementation and speed of customer conversion.

## Option Agreement with University of Liverpool for T3cDM

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. There would also be a strong clinical case for using the test to screen all individuals diagnosed with T3cDM for pancreatic cancer, as they are at significantly increased risk of being diagnosed with 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 pancreatic cancer test 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

On 24 May 2025, BARD1 announced that it had filed two new patent applications protecting its SubB2M and EXO-NET technologies. The EXO-NET patent application is directed at modifying EXO-NET to specifically capture exosomes released from cancers into the bloodstream. This has the potential to revolutionise the use of exosomes in cancer diagnosis.

Two patents were granted covering the BARD1 technology in the period including US patent 11,022,612 titled "BARD1 isoforms in lung and colorectal cancer and use thereof", and South Korean Patent 10-2016-7014869 titled "Lung cancer diagnosis".

## QUALITY AND REGULATORY UPDATE

During the quarter, BARD1 prepared for an annual audit of its ISO 13485:2016 Quality Management System (QMS). The Company was audited remotely (due to COVID-19 restrictions) by BSi on 8 July 2021 leading to successful ISO re-certification. The next major ISO audit will be in July 2022.

The Company continues to transition its QMS to align with the global medical device regulatory landscape, including the European IVDR (In Vitro Diagnostic Regulation), Global UDI (Unique Device Identification) barcodes for device traceability, and Global Risk Management (under ISO14971:2019).

BARD1 is also implementing a cloud based electronic QMS solution to support global regulatory harmonisation, continuous improvement, and efficient quality management of our product portfolio.

## CORPORATE UPDATE

On 4 June 2021, BARD1 announced an update on the legal proceedings by Tony Walker and former founding scientist of the Company, Dr Irmgard Irminger-Finger (Plaintiffs and, together, the Claim). The Company received from the Plaintiffs particulars, and proposed means of calculation, of their alleged loss and damages relating to the Claim and is reviewing it with its legal advisers. Although the calculations derive a potentially very significant amount of claimed loss and damage by the Plaintiffs, any such claim will ultimately turn on the evidence and the outcome of the legal proceedings at trial. The Company continues to dispute the basis of the Claim and has filed with the Supreme Court of Victoria a comprehensive defence.

Post quarter-end, on 7 July 2021, BARD1 released an investor presentation that was used to update shareholders, brokers and investors on the Company, its pipeline and commercialisation plans.

Post quarter end, on 23 July 21, BARD1 announced a successful \$15 million placement with strong demand from new and existing institutional and sophisticated investors in Australia and Hong Kong. Additionally, eligible existing shareholders will be offered the opportunity to participate in a Share Purchase Plan (SPP) to raise up to a further \$2 million on the same terms as the placement at \$1.55 per share, including 1 free quoted option for every 2 shares issued, exercisable at \$2.32 up until the expiry date of 24 August 2023. The funds raised from the placement and SPP will be primarily used to fund development and commercialisation of SubB2M tests for ovarian and breast cancers, commercialisation of EXO-NET products, working capital and costs associated with the Offers. Bell Potter acted as lead manager, Kidder Williams as corporate advisors and Minter Ellison as legal advisors to the capital raising.

## FINANCIAL UPDATE

BARD1 ended the financial year with a cash balance of \$5.0m. Operating cash receipts during the quarter included:

- \$644k R&D tax incentive refund;
- \$184k from the sale of hTERT product (year to date \$455k);
- \$48k from the Biomedical Translation Bridge (BTB) grant program supporting the development of SubB2M-based liquid biopsy tests to detect and monitor breast cancer; and
- \$4k in bank interest.

Net cash used in operating activities for the quarter was \$964k with the key contributors being:

- Research and Development (R&D) expenditure of \$867k (year to date \$2,873k);
- Non-R&D staff costs of \$288k (year to date \$1,648k);
- Administration and corporate costs of \$587k (year to date \$1,665k, including legal costs defending the Supreme Court Writ); and
- Patent fees of \$63k (year to date \$373k).

Payments to related parties of \$61k per section 6.1 of the Appendix 4C are for director fees and superannuation.

Further details are provided in the Appendix 4C attached.

*Authorised by the Company Secretary, Tony Di Pietro.*

ENDS

## COMPANY CONTACTS

**Dr Leeарne Hinch**  
CEO  
**E** [leearne@bard1.com](mailto:leearne@bard1.com)  
**M** +61 400 414 416

**Dr Geoff Cumming**  
Non-Executive Chairman  
**E** [geoff.cumming@bard1.com](mailto:geoff.cumming@bard1.com)  
**M** +61 417 203 021

## 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 diagnostic solutions for healthcare professionals and patients. BARD1 has commercialised the hTERT test used as an adjunct to urine cytology testing for bladder cancer and the EXO-NET pan-exosome capture tool for research purposes. Our cancer diagnostic pipeline includes tests in development for ovarian and breast cancers, and research-stage projects for prostate and pancreatic cancers. For more information on BARD1, see [www.bard1.com](http://www.bard1.com) and [www.exo-net.com](http://www.exo-net.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”)**

30 June 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	184	455
1.2 Payments for		
(a) research and development ( <i>including allocated staff costs</i> )	(867)	(2,873)
(b) patent fees	(63)	(373)
(c) advertising and marketing	(40)	(119)
(d) product manufacturing and operating costs	(3)	(74)
(e) staff costs ( <i>other than R&amp;D staff</i> )	(288)	(1,648)
(f) administration and corporate costs	(587)	(1,665)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	42
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	644	744
1.8 Other ( <i>Govt stimulus &amp; BTB Grant</i> )	52	219
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(964)</b>	<b>(5,292)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(50)	(438)
(d) investments	-	-
(e) intellectual property	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
(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
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(50)</b>	<b>2,683</b>

<b>3. Cash flows from financing activities</b>		
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
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)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>-</b>	<b>286</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	6,013	7,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(964)	(5,292)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(50)	2,683
4.4	Net cash from capital raising (item 3.10 above)	-	286
4.5	Effect of movement in exchange rates on cash held	-	3
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>4,999</b>	<b>4,999</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	978	1,992
5.2	Call deposits	4,021	4,021
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>4,999</b>	<b>6,013</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	61
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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.*

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
-	-
20	-
-	-
-	-

**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)	(964)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	4,999
8.3 Unused finance facilities available at quarter end (Item 7.5)	20
8.4 Total available funding (Item 8.2 + Item 8.3)	5,019
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>5</b>

*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 July 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.