

## QUARTERLY BUSINESS UPDATE

- **Commercial progress:**
  - hTERT receipts of \$221k for the period compared to \$184k for the previous quarter
  - EXO-NET<sup>®</sup> RUO evaluations progress with academic and industry partners
  - BARD1 autoantibody technology and data undergoing comprehensive review
- **Solid R&D progress:**
  - Proof-of-Concept (POC) achieved for SubB2M-based ELISA<sup>1</sup> for ovarian cancer in feasibility studies
  - Promising exosome-based ovarian cancer test data released by collaborator University of Queensland (UQ) using EXO-NET for isolation of exosomes
  - Dr Greg Rice appointed as CSO<sup>2</sup> to accelerate commercial development of diagnostic tests
- **Corporate initiatives:**
  - Capital raising of \$18.4m from a Placement and Share Purchase Plan (SPP) strengthening proforma cash balance to \$22m
- **Cash position:**
  - Net cash of \$17.2m received from share placement and SPP
  - Cash balance of \$20.4m as at 30 September 2021

**Melbourne, Australia, 29 October 2021:** BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or the **Company**), today released its Appendix 4C and Quarterly Business Update for the quarter ended 30 September 2021.

---

### COMMERCIALISATION UPDATE

Commercial activities during the quarter focused on support of the Company's hTERT and EXO-NET products.

#### hTERT ICC test

The Company received \$221k in hTERT receipts for the September quarter, compared to \$184k for the previous quarter.

The Company's commercial team continued to work with its hTERT distributors in the USA, Europe and South Korea to provide ongoing technical support and assist with new product evaluations by pathology laboratories. Distributors report that new customer acquisition continued to be hampered by COVID-19, with laboratories remaining focused on COVID testing and routine testing volumes were reduced.

The hTERT test is an immunocytochemistry (ICC) assay registered for use as a clinical diagnostic by pathology laboratories for the detection of human telomerase reverse transcriptase (hTERT) in cytopathology samples. It is used by pathologists as an adjunct to urine cytology to help resolve indeterminate cytology results and identify patients with increased risk of bladder cancer.

#### EXO-NET<sup>®</sup> RUO commercialisation

The Company is progressing evaluations of the EXO-NET RUO<sup>3</sup> product by leading research groups and industry parties, in Australia and overseas. Feedback from researchers continues to support EXO-NET's speed, purity and yield advantages over existing exosome isolation technologies.

Additionally, the Company is continuing discussions with potential commercial partners to manufacture and distribute EXO-NET RUO to expand its international reach and support sales, marketing, and

---

<sup>1</sup> Enzyme-linked immunosorbent assay (ELISA)

<sup>2</sup> Chief Scientific Officer (CSO)

<sup>3</sup> Research Use Only (RUO)

distribution of the product for research applications, which are expected to result in future international peer-reviewed publications supporting the utility of EXO-NET in various exosome research applications.

In November 2021, BARD1 will sponsor and attend the virtual Australia & New Zealand Society of Extracellular Vesicles (ANZSEV) Symposium that replaced the Conference now rescheduled to 2022 (due to COVID restrictions).

EXO-NET RUO is a pan-exosome capture tool for isolation of exosomes from body fluids including plasma, urine, and saliva.

---

## RESEARCH AND DEVELOPMENT (R&D) UPDATE

During the quarter, the Company has prioritised its R&D activities to achieve key milestones for the SubB2M, NETs and BARD1 programs. As part of the Company's continuous improvement program, new electronic quality management system (eQMS) systems for processing and storage of research data and clinical samples have been implemented to enable effective alignment of R&D activities with global quality and regulatory requirements. Key priorities include establishing an in-house SubB2M immunoassay and the generation of a robust data package to facilitate commercial assay development by an industry partner, and review of the BARD1 autoantibody program.

### SubB2M program

During the quarter, the Company continued to advance its SubB2M program to transfer the research-stage SubB2M test from a research-use SPR<sup>4</sup> platform to a commercial-use ELISA platform for the potential monitoring and detection of breast and ovarian cancers. The current development program is focused on developing improved CA125 and CA15.3 tests for monitoring of ovarian and breast cancers.

On 17 August 2021, BARD1 announced that proof-of-concept (POC) had been achieved for its SubB2M/CA125<sup>5</sup> ELISA-based test for ovarian cancer. BARD1's collaborator, the Institute for Glycomics at Griffith University (Griffith), demonstrated that an initial SubB2M/CA125 assay could detect CA125-Neu5Gc in serum from stages I-IV ovarian cancer (OC) patients compared to healthy controls at biologically relevant levels. Professor Mike Jennings of Griffith said: "We have successfully achieved initial assay design and feasibility testing and will now advance to the optimisation phase for the SubB2M/CA125 test."

Achievement of this POC milestone supports the further development of potential SubB2M tests for ovarian, breast, prostate and other cancers. The next steps for the SubB2M ovarian cancer program are to complete the optimisation phase with testing of OC samples and healthy controls compared to SPR, followed by clinical testing to demonstrate the sensitivity and specificity of the SubB2M/CA125 test for detection of ovarian cancer across all stages compared to CA125 alone in archived samples from the Victorian Cancer Biobank.

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

### NETs program

The Company is advancing research to evaluate its revolutionary EXO-NET technology to isolate exosomes for potential diagnostic and therapeutic applications. Several EXO-NET pan-exosome and custom prototypes have been built, tested and compared to competitor exosome isolation technologies by the Company's US-based exosome research team. This research is ongoing, with several collaborations being progressed with academic and industry groups, with the aim of in-licensing new intellectual property for development of in-house exosome-based diagnostics, or out-licensing pan-exosome or customised EXO-NET prototypes to partners for use in commercialisation of specific exosome-based diagnostics and therapeutics.

On 28 July 2021, BARD1 announced that its collaborator University of Queensland (UQ) had released promising data for its potential exosome-based ovarian cancer test. BARD1's EXO-NET RUO product was

---

<sup>4</sup> Surface Plasmon resonance (SPR)

<sup>5</sup> CA125 = Cancer Antigen 125 biomarker used for the monitoring of ovarian cancer

used by the UQ researchers to isolate exosomes from the blood of ovarian cancer patients within 15 minutes, with high purity and yield. Assoc Prof Carlos Salomon from the University of Queensland said: “EXO-NET provides a simple and rapid exosome capture technology, which has been used with our ovarian cancer test developed at UQ and has great potential for clinical applications.” BARD1’s agreement with UQ’s commercialisation company, UniQuest, provides BARD1 with an exclusive option to licence the technology developed at UQ.

The Company is currently preparing a paper using data collected from its in-house comparison studies of EXO-NET RUO to competitor exosome capture tools for publication. Publication of both in-house and external collaborator EXO-NET data are expected to generate research interest in EXO-NET and lead to further research collaborations, potential commercial licensing deals and/or sales of EXO-NET.

EXO-NET is an exosome capture platform based on the Company’s proprietary Molecular NET technology. Exosomes are extracellular vesicles that are released from cells, including cancer cells, into body fluids. Clinical interest in exosomes has grown exponentially due to their commercial potential as both disease biomarkers for diagnostics and novel targets for therapeutics. EXO-NET is a proprietary matrix containing antibodies to exosomal surface markers that is designed to capture exosomes from body fluids rapidly, with high yield and purity. The EXO-NET matrix can be customised by our expert research team to capture specific subsets of exosomes and be applied to beads or any surface to enable capture, release and scalable isolation of exosomes for potential exosome-based diagnostic and therapeutic applications.

### **BARD1 program**

The Company has initiated a comprehensive internal and external review of the BARD1 autoantibody (AAb) program and data from previous BARD1 AAb studies to inform further assay design, research direction and future studies. Additionally, the Company is evaluating alternative BARD1 biomarker approaches in combination with its NETs technology.

Previous research has identified autoantibodies (AAbs) to BARD1 splice variants in all stages of some cancers, including the early stages of ovarian, breast and lung cancers. BARD1 AAbs potentially reflect the early immune response to tumour formation, that may enable BARD1 AAb tests to detect cancer earlier across all cancer stages before symptoms appear. BARD1 AAb tests have been previously investigated to measure autoantibodies to BARD1 variants and their ability to predict the presence or absence of a specific cancer using an algorithm.

### **Appointment of new CSO**

On 16 September 2021, BARD1 announced the appointment of leading medical researcher Dr Greg Rice as Chief Scientific Officer (CSO), effective 20 September 2021.

Dr Greg Rice PhD, BSc (Hon), MHA, Grad Dip Mgt has over 30 years’ experience in oncology, perinatology, exosome-based research, clinical translational research, IVD development and commercialisation. He has held senior academic appointments, co-founded hospital-based clinical research centres in both oncology and perinatology and co-founded and led diagnostic companies. He has held numerous academic leadership positions including at the University of Queensland (UQ), Baker Heart and Diabetes Institute, University of Melbourne, and Monash University. As Director of the UQ Centre for Clinical Diagnostics (CCD), he implemented ISO17025 quality management system, secured NATA accreditation and established an exosome research facility to evaluate the clinical utility of extracellular vesicles as liquid biopsies, IVDs and therapeutics. Additionally, he was a Founding Director and CSO of diagnostics company HealthLinx Ltd and more recently CEO of Pregnostica SpA.

Dr Peter French, previous CSO, has transitioned to a consulting role with the Company as Strategic Technology Advisor, where he will provide ongoing strategic advice, scientific expertise, and technical support.

---

## **QUALITY AND REGULATORY UPDATE**

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

---

## CORPORATE UPDATE

The Company completed a successful capital raising of \$18.4 million, including a \$15 million placement to institutional and sophisticated investors on 23 July 2021, and a \$3.4 million Share Purchase Plan (SPP) to eligible existing shareholders on 23 August 2021. Both capital raising initiatives were offered on the same terms with a total of 11,878,205 new shares issued at \$1.55 per share including 9,677,420 shares under the Placement and 2,200,785 shares under the SPP. Additionally, one free quoted option was offered for every two shares issued, resulting in 5,909,965 options issued that are exercisable at \$2.32 up until the expiry date of 24 August 2023. The BARD1 directors and CEO took up their maximum entitlement under the SPP as existing shareholders.

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 September quarter with a cash balance of \$20.4m. The increase in the cash balance compared to the previous quarter (\$5m at 30 June 2021) was a result of capital raised via the Placement and SPP (a total of \$18.4m, before costs).

Operating cash receipts during the quarter included:

- \$221k from the sale of hTERT product;
- \$11k 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 \$1.8m with the key contributors being:

- Research and Development (R&D) expenditure of \$689k;
- Non-R&D staff costs of \$475k;
- Administration and corporate costs of \$689k (including legal costs defending the Supreme Court Writ); and
- Patent fees of \$102k.

Net cash received from financing activities during the quarter was \$17.2m, comprising:

- Placement to new and existing institutional and sophisticated investors in Australia and Hong Kong, raising \$15m;
- SPP offer to existing shareholders, raising \$3.4m;
- (Less) transactions costs related to the Placement and SPP (\$1.2m).

Payments to related parties of \$62k per section 6.1 of the Appendix 4C were 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 Learne 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 September 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	221	221
1.2 Payments for		
(a) research and development ( <i>including allocated staff costs</i> )	(689)	(689)
(b) patent fees	(102)	(102)
(c) advertising and marketing	(35)	(35)
(d) product manufacturing and operating costs	(24)	(24)
(e) staff costs ( <i>other than R&amp;D staff</i> )	(475)	(475)
(f) administration and corporate costs	(689)	(689)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	4
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other ( <i>Govt stimulus &amp; BTB Grant</i> )	11	11
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,778)</b>	<b>(1,778)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(8)	(8)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 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	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(8)</b>	<b>(8)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	18,411	18,411
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(1,212)	(1,212)
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>17,199</b>	<b>17,199</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	4,999	4,999
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,778)	(1,778)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(8)	(8)
4.4	Net cash from capital raising (item 3.10 above)	17,199	17,199
4.5	Effect of movement in exchange rates on cash held	1	1
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>20,413</b>	<b>20,413</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	8,392	978
5.2	Call deposits	12,021	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>20,413</b>	<b>4,999</b>

**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	62
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

**Current quarter  
\$A'000**

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 <b>Total financing facilities</b>	-	-

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.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,778)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	20,413
8.3 Unused finance facilities available at quarter end (Item 7.5)	20
8.4 Total available funding (Item 8.2 + Item 8.3)	20,433
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	11

*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: 29 October 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.