

QUARTERLY BUSINESS UPDATE

• Strong progress across the Group's cancer R&D programs:

- o Initiated independent validation study of BARD1-Ovarian at Griffith University
- o Completed transfer of BARD1 technology and biobank to Australia
- Executed collaborative research agreements with Griffith University to develop SubB2M-based tests for monitoring ovarian and breast cancers
- Commenced in-house SubB2M research programs for prostate and pancreatic cancers
- RUO EXO-NET product on-track for commercial launch in 2021
- New high-volume hTERT user: BARD1's US distributor gains new high-volume customer for hTERT ICC test
- New Patent Granted: Chinese patent granted covering hTERT technology and hTERT assay
- **Cost-savings achieved:** Administrative costs savings realised in full during the quarter, estimated to be \$450k per annum
- Share Consolidation: 30:1 share consolidation implemented
- Cash position: Cash balance of \$7.3m at 31 December 2020

Melbourne, Australia, 29 January 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 December 2020.

COMMERCIALISATION UPDATE

BARD1 has made good progress in the last quarter advancing the Company's game changing technologies closer toward successful commercialisation. Recapping, the table below summarises the four program areas the Company is advancing:



BARD1 and SubB2M commercialisation

The BARD1 and SubB2M biomarker programs represent a significant opportunity to address a major unmet medical need in early cancer detection and monitoring. As part of the Company's commercialisation activities for these two programs, engagement with Payors and Insurers in the US was initiated to determine their clinical data requirements to support reimbursement of the tests. The Company expects to receive initial feedback by mid 2021.

The Company is in early-stage discussions with numerous potential Laboratory partners who could establish these tests as Laboratory Developed Tests (LDTs) in the USA. The Company's

commercialisation strategy for these tests is to first launch them as LDTs, followed by an FDA submission and IVD approval.

RUO EXO-NET commercialisation

BARD1's first commercial embodiment of the NET Technology, **EXO-NET**[™], is on track to be launched as a Research Use Only (RUO) product in the second quarter of CY2021. EXO-NET has been specially designed to capture exosomes from body fluids and cell culture for diagnostic and therapeutic purposes. According to Grand Review Research the exosome market is expected to reach US\$2.3 billion by 2030 growing at a CAGR of 18%. Positioning EXO-NET[™] RUO as a research tool has the potential to embed the technology into the discovery, research and development phases for multiple liquid biopsy and therapeutic applications. This should also generate multiple new publications which will highlight the value EXO-NET[™] can deliver in exosome isolation and development of potential exosome-based products. Importantly, this may lead to future licensing agreements for development and commercialisation of exosome-based products incorporating the Molecular Net technology. During the quarter BARD1 has finalised in-house manufacturing procedures and packaging enabling product availability for launch in Q2 CY2021. The Company continues to advance its research collaborations with the University of Sydney, University of Queensland, Minomic and VivaZome Therapeutics. These collaborations highlight the flexibility and potential advantages of EXO-NET for exosome isolation across a range of applications.

hTERT business

Sales of the Company's 'in-market' product **hTERT**, a test that is used as an adjunct to urine cytology in the diagnosis of bladder cancer, continue to be impacted by the reduction in routine pathology demand, particularly in the USA. Quest Diagnostics, one the largest pathology providers in the US, reported a 49%^{III} drop in adult primary care visits leading to a significant deferral of routine pathology demand. There is evidence that the routine testing market is beginning to recover which, in conjunction with BARD1's previously announced strategy to focus on high-volume customers in the USA, should provide a lift in hTERT revenues.

In November, BARD1 announced that the Company's US distributor, StatLab, had secured their first new high-volume customer. BARD1's commercial team has prepared a target list of potential additional high-volume customers and has commenced promotion of hTERT to those laboratories. The company is also restructuring its sales and technical support resources to more efficiently support this new strategy.

Outside of the US, in conjunction with our distributors, validation and optimisation studies for hTERT have commenced at several key Reference Centres in Greece, Sweden and Israel.

¹¹Mehrotra A, Chernew M, Linetsky D, Hatch H., The impact of the COVID-19 pandemic on outpatient visits: a rebound emerges. To the Point (blog), The Commonwealth Fund. Updated May 19, 2020. doi: doi.org/10.26099/ds9e-jm36

RESEARCH AND DEVELOPMENT (R&D) UPDATE

BARD1 continues to progress its multi-product pipeline based on its game changing BARD1, NET, SubB2M and hTERT technologies. The Company's R&D programs focus on areas with significant unmet needs, particularly for early cancer detection. Our technologies provide potential significant commercial and clinical benefits for patients, the healthcare system and shareholders.

The Company made solid progress across our BARD1 autoantibody (AAb), SubB2M, NETs and hTERT programs during the quarter.

BARD1 autoantibody program

In December, the Company initiated its independent BARD1-Ovarian cancer validation study at Griffith University to test the robustness of the peptide algorithm in new samples of ovarian cancer and healthy controls. Reagents, antibody kits, controls and clinical samples were obtained and assembled prior to the end of December, and the assay work commenced in mid-January 2021. Analysis of the results is expected to be completed in the first quarter of the 2021 calendar year.

BARD1 completed the transfer of its BARD1 autoantibody research and sample biobank from UNIGE to Australia in December 2020. Following ethics approval being obtained in December, additional clinical samples are planned to be obtained from the Victorian Cancer Biobank (VCB) in the first quarter of CY2021

for the BARD1 autoantibody follow-up validation studies, as well as for other assay developments utilising EXO-NET and SubB2M throughout 2021, as described below.

NETs program

During the quarter, BARD1 accelerated the commercial development of the Company's exosome capture product, RUO EXO-NET, towards its planned commercial launch for sale to academia, research institutions and biopharma in 2021. EXO-NET prototypes were supplied to researchers at the University of Sydney and University of Queensland for evaluation in studies on cancer-associated exosomes. Discussions were commenced with a leading global company in the exosome field to introduce the party to EXO-NET's unique features and benefits for exosome research.

BARD1 also progressed its collaboration with Melbourne-based VivaZome Therapeutics for use of customised EXO-NETs in the production of their proprietary therapeutic exosomes in development for therapeutic applications. Initial results from this collaboration are expected by the third quarter of the 2021 calendar year.

SubB2M program

SubB2M, is a recombinant protein designed to specifically bind to a unique cancer-associated sugar. BARD1 is developing a range of cancer assays based on the use of SubB2M. In December 2020, BARD1 executed a 2-year collaborative research agreement with Griffith University to develop a range of proprietary new SubB2M-based liquid biopsy assays for monitoring of treatment response and recurrence of breast and ovarian cancers.

In addition, BARD1 commenced its own in-house ELISA development using SubB2M for monitoring of other cancers including prostate and pancreatic cancer. Following a successful ethics application, samples will be obtained from the VCB in the first quarter of CY2021, with assay development to follow shortly thereafter. 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.

hTERT study

The Company has commenced the evaluation of over 100 clinical immunocytochemical (ICC) specimens with the aim of 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 is expected by June 2021.

OTHER INITIATIVES

Intellectual Property (IP) Portfolio Update

Chinese Patent number ZL 201580008934.2 entitled 'Method of Detecting Cancer' was granted by the China Patent and Trademark Office on December 2nd, 2020. This patent covers the use of the Company's hTERT antibody to resolve inconclusive cytology and detect malignant cells. It protects the Company's hTERT test, used as an adjunct to urine cytology, in China until 23 September 2035.

CORPORATE UPDATE

Share Consolidation

At BARD1's 2020 AGM, shareholders approved a consolidation of the Company's ordinary shares on the basis of 1 ordinary share for every 30 ordinary shares held. The consolidation completed on 7 December 2020. The total number of ordinary shares on issue reduced to 79,817,772 from 2,394,530,384. Shareholders % holding and value in the company remained unchanged. Shareholders were notified by the company's share register of their new holding balances. Both share option holdings and performance share holdings were reduced in the same proportion.

FINANCIAL UPDATE

The company's cash balance at 31 December 2020 was \$7.3m. The following provides a reconciliation of the movement in the cash balance recorded from 30 June 2020 to 31 December 2020:

Cash at the beginning of the half-year	\$7,319k
Cash used in operating activities during the half-	(\$2,840k)
year	
Cash received via the merger with Sienna	\$3,769k
Payment of the final expenses associated with the	(\$645k)
merger with Sienna	
Property, plant and equipment purchases	(\$345k)
Cash at the end of the half-year	\$7,258k

Operating cash receipts during the quarter included \$152k from the sale of hTERT product (Quarter 1 - \$77k), receipts from both the Federal and Victorian government totalling \$101k in COVID-19 support (Quarter 1 - \$48k), and bank interest \$10k (Quarter 1 - \$20k).

Net cash used in operating activities for the quarter was \$1,382k (Quarter 1 - \$1,458k) with the key contributors being:

- Research and Development (R&D) expenditure of \$716k (Quarter 1 \$474k) to support the development of the projects discussed under 'RESEARCH & DEVELOPMENT (R & D) UPDATE' above;
- Non-R&D staff costs of \$419k (Quarter 1 \$464k);
- Administration and corporate costs of \$375k (Quarter 1 \$442k); and
- Patent fees of \$ \$96k (Quarter 1 \$156k).

During the quarter ending 31 December 2020 the company purchased a high-spec Keyense VR Microscope to support the continued development of the NETs technology, which was the major contributor to the \$300k recorded for the investment in property, plant and equipment (net cash used in investing activities).

Payments to related parties of \$145k per section 6.1 of the Appendix 4C are for director costs, including executive director salaries, non-executive director fees and Superannuation Guarantee contributions (Quarter 1 - \$157k).

The benefits of administrative efficiencies and synergies, a significant benefit of the merger between BARD1 and Sienna Cancer Diagnostics, were realised in full during the quarter ending 31 December 2020. The removal of duplicate overhead expenses, and alignment of accounting, administration, banking and governance policies and procedures, has saved an estimated \$450k per annum in the areas of accounting and auditing, legal, ASX listing, and share registry fees.

Further savings of over \$450k per annum will begin to take affect from February 2021 with the transfer of the majority of BARD1 research & development activities from Switzerland to Australia.

Further details are provided in the Appendix 4C attached.

Authorised by the Company Secretary, Tony Di Pietro.

ENDS

COMPANY CONTACTS

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ABOUT BARD1 LIFE SCIENCES LTD

BARD1 Life Sciences Ltd (ASX:BD1) (**BARD1** or the **Company**) 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 for healthcare professionals and patients. The cancer diagnostics portfolio includes the commercialised hTERT test used as an adjunct to urine cytology testing and diagnostic tests in development for ovarian, breast, lung, prostate and pancreatic cancers. For more information on BARD1, see <u>www.bard1.com</u>.

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 DECEMBER 2020

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	152	229
1.2	Payments for		
	(a) research and development (<i>including</i> allocated staff costs)	(716)	(1,190)
	(b) patent fees	(96)	(252)
	(c) advertising and marketing	(39)	(55)
	 (d) product manufacturing and operating costs 	_	(51)
	(e) staff costs (other than R&D staff)	(419)	(883)
	(f) administration and corporate costs	(375)	(817)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	10	30
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (Govt stimulus)	101	149
1.9	Net cash from / (used in) operating activities	(1,382)	(2,840)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(300)	(345)
	(d) investments	-	-
	(e) intellectual property	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 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 (Merger transaction costs)	-	(645)
	Other (Sienna Cancer Diagnostics Cash Balance)	-	3,766
2.6	Net cash from / (used in) investing activities	(300)	2,776

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	-	
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	-	

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,940	7,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,382)	(2,840)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(300)	2,776
4.4	Net cash from capital raising (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	3
4.6	Cash and cash equivalents at end of period	7,258	7,258

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	787	569
5.2	Call deposits	6,471	8,371
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)	7,258	8,940

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

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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

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
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)	(1,382)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	7,258
8.3	Unused finance facilities available at quarter end (Item 7.5)	20
8.4	Total available funding (Item 8.2 + Item 8.3)	7,278
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	5

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 January 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.