

QUARTERLY BUSINESS UPDATE

- **Completed Sienna acquisition:** Scheme of Arrangement implemented with BARD1 acquiring Sienna Cancer Diagnostics (Sienna), expanding technology and product portfolio, and strengthening management to execute the business plan
- **Strategic business review completed:** Business review focused on realising synergies, advancing the R&D pipeline and increasing revenue
- **Cost-savings being realised:** BARD1 is on track to realise over \$1.1m in cost-savings from operational synergies and restructuring post-merger
- **Completed optimisation of v2 BARD1 Kit:** Successful evaluation of the optimised BARD1 kit in ovarian cancer samples on the Luminex platform
- **Awarded BTB Funding for SubB2M program:** Received \$372,654 in grant funding to develop, validate and commercialise SubB2M-based liquid biopsy tests to detect and monitor breast cancer
- **Advanced RUO EXO-NET product:** New RUO EXO-NET product for research purposes expected to be commercial-ready in 2Q CY21
- **New Patent Granted:** Key European patent granted and validated for BARD1 technology covering a diagnostic kit for breast or ovarian cancer
- **Cash position:** Cash balance of \$8.9m at 30 September 2020

Melbourne, Australia, 30 October 2020: 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 September 2020.

CORPORATE UPDATE

Completion of Sienna acquisition

On 28 July 2020 the acquisition of Sienna and merger into BARD1 was completed under a Scheme of Arrangement (Scheme) whereby Sienna shareholders received 13 new fully paid ordinary shares in BARD1 for every 5 fully paid shares held in Sienna at 7:00pm on 23 July 2020. As part of the Scheme, all fully paid ordinary shares in Sienna were transferred to BARD1 and Sienna became a wholly owned subsidiary of BARD1 and was removed from the official list of the ASX.

The acquisition of Sienna and merger into BARD1 created an Australian diagnostics company with an experienced Board and leadership team and innovative cancer diagnostics portfolio of marketed and development-stage products. The Company's initial focus is on delivering novel diagnostics for early detection of cancer to save patient lives.

Board & Management changes

Following completion of the Sienna acquisition, the Company appointed Dr Geoffrey Cumming as Non-Executive Chairman and Ms Helen Fisher as Non-Executive Director, with Mr Peter Gunzburg resigning as Non-Executive Chairman effective 28 July 2020.

The executive team was also strengthened with the appointments of Mr Carl Stubbings as Chief Operations Officer (COO) and Tony Di Pietro as Chief Financial Officer (CFO)/Company Secretary on 28 July 2020, and Dr Peter French as Chief Scientific Officer (CSO) on 17 August 2020 after an extensive executive search. These executive appointments and additional R&D, quality, sales and business development staff gained through the Sienna acquisition improve the Company's ability to execute its business plan.

Relocation to Melbourne

BARD1 relocated its headquarters and CEO Dr Learne Hinch to Melbourne as a result of the Sienna acquisition.

Strategic Business Review & Integration Activities

BARD1 completed a strategic business review of its resources, capabilities and operations during the quarter with a focus on integrating our operations, executing our growth strategy, advancing our R&D pipeline towards value-generating development and commercial milestones, increasing revenue and growing shareholder value. The Company aims to develop best-in-class diagnostic tests for healthcare professionals and patients using its platform technologies for the prediction, screening, diagnosis, theranosis and monitoring of cancers with significant unmet needs. Further details of this review will be provided before and at the Annual General Meeting.

Additionally, management focused on achieving operational efficiencies and realising synergies, including alignment of accounting, administration, banking and governance policies and procedures. Cost savings envisaged from the merger have begun to be realised with savings of up to \$450k per annum in the areas of accounting and auditing, legal, and ASX listing and share registry fees. Additional savings of over \$230k per annum in staff and contractor changes have already been achieved, and further savings of over \$450k per annum are expected to be realised from restructuring initiatives including transferring the BARD1 research from Switzerland to Australia in calendar year 2021.

COMMERCIAL UPDATE

BARD1's strategic review of the hTERT business during the quarter has resulted in changes to its strategic marketing plan and implementation of additional sales and product support initiatives aimed at driving future hTERT revenues in the USA and other key markets.

hTERT ICC Test

The hTERT Test is an immunocytochemistry (ICC) assay that detects hTERT, a component of telomerase, which is upregulated in most human epithelial cancers. The test is used as an adjunct to urine cytology, assisting in the diagnosis of bladder cancer.

The hTERT test has been commercialised and is generating revenue in the USA. Distributors have also been appointed in European, Asian and South American countries to expand our global footprint.

In the USA, BARD1 is working with our distributor StatLab Medical Products to implement key changes to our marketing strategy to increase sales of hTERT. Advanced discussions have been held with numerous high-volume customers to establish the use of hTERT as part of their routine urine cytology. To further enhance hTERT adoption the Company is collaborating with Key Opinion Leaders and Key Users to publish white papers and peer reviewed publications highlighting the use of hTERT as a routine adjunct to bladder cancer diagnosis. These changes in our US strategy, combined with the previously announced initiatives, are expected to lead to increased sales of hTERT in the USA.

In Europe, our sales team continues to work with our distributors to establish hTERT in major reference laboratories and generate initial sales. Modest sales have been recorded in this region, with sales expected to grow during FY2021. Notably, the sales team has been working closely with recently appointed Israeli distributor Zotal to provide product training to its sales team and establish the hTERT test in a leading hospital. Discussions continue with potential distribution partners in the larger EU markets of Germany, France, Italy and Spain.

In Asia, our Quality & Regulatory Manager has been working closely with our distributors and regulatory consultants in China and South Korea to finalise the regulatory process and gain approval for marketing of hTERT in these countries. Once approval is granted, distributors in both countries are committed to placing an initial substantial sales order in accordance with their distribution agreements.

In other regions, work continues with newly appointed distributors to progress commercialisation.

The global COVID-19 pandemic continues to have an impact on routine laboratory testing worldwide with many laboratories switching to COVID-19 testing. This reduction in routine laboratory testing includes urine cytology and has negatively impacted expected growth in hTERT revenues, with \$77k of product income received during the quarter.

Business Development

The Company's business development team continues to seek partnering opportunities with diagnostic and biopharmaceutical companies for collaboration and licensing of BARD1's technologies for use in diagnostic and therapeutic applications. Successful collaborations have the potential to deliver significant value through future upfront licensing fees, milestone and royalty payments.

RESEARCH AND DEVELOPMENT (R&D) UPDATE

BARD1's strategic review of its expanded life science technologies and diagnostic pipeline product portfolio prioritised R&D activities to 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 important progress in our BARD1 autoantibody (AAb), SubB2M and EXO-NET programs during the quarter.

BARD1 autoantibody program

Splice variants of the BARD1 protein play an important role in cancer formation, progression and prognosis. Autoantibodies to these BARD1 splice variants have been found in all stages of cancer, including the early stages (I and II), before symptoms occur. BARD1 AAb tests are being developed to measure these autoantibodies to BARD1 variants and predict the presence or absence of a specific cancer using an algorithm.

During the quarter, our collaborator, the University of Geneva (UNIGE), completed a study to evaluate the reproducibility and accuracy of the new pilot version 2 (v2) Research Use Only (RUO) BARD1 kits on the Luminex platform in previously tested samples of ovarian cancer cases and healthy controls. As announced in September, the results showed a strong correlation between the peptide signals from the optimised RUO BARD1 kit developed on the Luminex platform compared with previous data on the Meso Scale Diagnostics (MSD) platform using the same samples. Further analysis of the data indicated that the number of peptides required for the test could be reduced while maintaining high levels of discrimination between ovarian cancer patients and controls.

This was an important milestone for BARD1, enabling us to advance the development of a commercial BARD1 AAb test for ovarian cancer on the Luminex platform. The Luminex platform is widely used in pathology laboratories globally. Thermo Fisher Scientific was contracted to develop the RUO BARD1 kit under a development agreement.

The Company is now moving forward with an independent BARD1-Ovarian cancer validation study at Griffith University to test the robustness of the algorithm in new samples of ovarian cancer and healthy controls. The study is expected to commence in November 2020 and be completed in the first quarter of the 2021 calendar year, once the new samples are received from the Victorian Cancer Biobank.

BARD1 has also initiated the transfer of its BARD1 AAb research and sample biobank from UNIGE to Australia. The transfer is expected to be completed by December 2020 and will enable the Company to conduct further development of the BARD1 AAb technology in our Australian facility under ISO 13485 quality management system. Undertaking the work in Australia should accelerate the program, reduce costs and ensure we fully benefit from the Australian Government Research and Development Tax Incentive (R&DTI).

The Company is also on-track with plans to further optimise and validate the BARD1-Breast cancer test on the Luminex platform, commencing in the first half of the 2021 calendar year. The BARD1-Breast and BARD1-Ovarian cancer tests for early detection of breast and ovarian cancers have the potential to significantly improve treatment, health and survival outcomes for this important unmet clinical need in women's health.

EXO-NET™ program

EXO-NET is an exosome capture technology based on the Company's proprietary SIEN-NET™ platform. Exosomes are extracellular vesicles that are shed from cells, including cancer cells, and are found abundantly in the blood stream. Clinical interest in exosomes has grown exponentially due to their

significant commercial potential as both cancer biomarkers for diagnostic applications and as novel therapeutics.

EXO-NET is a matrix that is designed to capture exosomes from body fluids rapidly, with high yield and purity. The EXO-NET matrix is applied to magnetic beads for ease of use by researchers. During the quarter, BARD1 accelerated the commercial development of the Company's Research Use Only (RUO) EXO-NET product. Commercialising EXO-NET as an RUO product has the potential to embed the technology into the discovery, research and subsequent product development phases for multiple exosome-based diagnostics and therapeutics, providing an additional revenue stream for the Company. Discussions with contract manufacturers and research product distributors are underway with a target of the second quarter of the 2021 calendar year for the product being launched for sale to academia, research institutions and biopharma.

BARD1's core focus for EXO-NET is the internal development and commercialisation of exosome-based liquid biopsies for cancer. An initial focus to complement this strategy is the development and manufacture of customised EXO-NET products for use by collaborators in the development of non-core exosome-based diagnostic and therapeutic products.

A customised RUO EXO-NET product has been produced to support the Company's collaboration with Minomic International for the development of a novel liquid biopsy test for pancreatic cancer. Initial results on this collaboration are expected by the second quarter of the 2021 calendar year.

BARD1 also has an exciting collaboration with Melbourne-based VivaZome Therapeutics for use of EXO-NET and the broader SIEN-NET technology in the capture and manufacture of VivaZome's proprietary pro-angiogenic exosomes in development for therapeutic applications. Initial results on this collaboration are expected by the third quarter of the 2021 calendar year.

SubB2M program

SubB2M is a recombinant protein that specifically detects a sugar (called Neu5Gc) that is only found on cancer cells and cancer-associated biomolecules. SubB2M can be used as a probe to detect a wide range of cancers. The Company has the exclusive worldwide license to SubB2M for cancer diagnostics from the University of Adelaide.

On 3 September 2020, BARD1 announced that it had been awarded \$372,654 in competitive grant funding from MTP Connect under the Biomedical Translation Bridge (BTB) program to develop, clinically evaluate and commercialise liquid biopsy tests to detect and monitor breast cancer using its proprietary SubB2M cancer-specific probe.

Previous pilot clinical studies at the University of Adelaide and Griffith University showed that SubB2M detected cancers with 100% sensitivity and specificity for mid to late-stage cancers, and >95% specificity and 100% sensitivity for early-stage cancers. There is also evidence that the cancer-specific sugar detected by SubB2M is present in a wide range of other solid human tumours, providing the Company with the opportunity to develop a range of novel, SubB2M-based, cancer diagnostic tests.

To this end, BARD1 has advanced plans to develop a range of proprietary new SubB2M-based liquid biopsy tests, in collaboration with Griffith University or in-house, for monitoring of treatment response and recurrence of breast, ovarian, prostate and pancreatic cancers using SubB2M alone or in combination with novel or existing cancer biomarkers. 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.

OTHER INITIATIVES

Intellectual Property (IP) Portfolio Update

European Patent (EP) number 2619218, titled "Kits for detecting breast or ovarian cancer in a body fluid sample and use thereof", was granted by the European Patent Office (EPO) on 29 April 2020 and validated in France, Germany, Italy, Spain, Switzerland and the United Kingdom during the quarter, providing enforceable IP protection in these countries.

The issued EP 2619218 claims are directed to kits comprising peptides from BARD1 isoforms for detecting autoantibodies associated with breast or ovarian cancer. The patent application was filed on 23 September 2011 and is due to expire on 23 September 2031.

Biotechnology Industry Projects

The Company continues to work with the University of Melbourne and Monash University on industry projects where students collaborate with their industry partner to develop innovative strategies and tangible outcomes to real world technology and business challenges.

Master of Biotechnology students at the University of Melbourne have been focused on identifying product opportunities for the Company's SIEN-NET technology under the guidance of BARD1 Associate Principal Scientist Dr Catriona Sinclair. The students recently presented their market research, technical analysis and commercialisation opportunities to BARD1 management. Dr Sinclair said: "I was really impressed by the depth of analysis and insights on the circulating nucleic acid opportunity that the students prepared."

The final year Global Executive MBA students at Monash have been working with BARD1 Business Development Manager Minesh Lalla on new market opportunities for our in-market hTERT product. The students will present their work to the Company in November 2020.

FINANCIAL UPDATE

BARD1 ended the quarter with a cash balance of \$8.9m. The following provides a reconciliation of the movement in the cash balance recorded at the end of June 2020:

Cash at the beginning of the quarter	\$7,319k
Cash used in operating activities during the quarter	(\$1,458k)
Cash received via the merger with Sienna	\$3,769k
Payment of the final expenses associated with the merger with Sienna	(\$645k)
Property, plant and equipment purchases	(\$45k)
Cash at the end of the quarter	\$8,940k

Net cash used in operating activities for the quarter was \$1,458k with the key contributors being payments for:

- Research and Development (R&D) expenditure of \$474k;
- Patent fees of \$156k;
- Non-R&D staff costs of \$464k; and
- Administration and corporate costs of \$442k.

Operating cash receipts during the quarter included \$77k of hTERT product income, \$48k of COVID-19 stimulus payments from both the Federal and Victorian governments, and \$20k of interest.

Net cash from investing activities was \$3,076k which includes the cash received from the merger with Sienna, less the payment of the final expenses associated with the merger with Sienna (\$645k), and \$45k for building improvements and the purchase of laboratory equipment.

Further details are provided in the Appendix 4C attached.

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

Authorised by the Company Secretary, Tony Di Pietro.

ENDS

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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 lifesaving 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 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")

30 SEPTEMBER 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	77	77
1.2 Payments for		
(a) research and development (<i>including allocated staff costs</i>)	(474)	(572)
(b) patent fees	(156)	(156)
(c) advertising and marketing	(16)	(16)
(d) product manufacturing and operating costs	(51)	(51)
(e) staff costs (<i>other than R&D staff</i>)	(464)	(366)
(f) administration and corporate costs	(442)	(442)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	20	20
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</i>)	48	48
1.9 Net cash from / (used in) operating activities	(1,458)	(1,458)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(45)	(45)
(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 (<i>Merger transaction costs</i>)	(645)	(645)
	Other (Sienna Cancer Diagnostics Cash Balance)	3,766	3,766
2.6	Net cash from / (used in) investing activities	3,076	3,076

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	7,319	7,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,458)	(1,458)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	3,076	3,076
4.4	Net cash from capital raising (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	3	3
4.6	Cash and cash equivalents at end of period	8,940	8,940

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	569	569
5.2	Call deposits	8,371	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)	8,940	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
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

157

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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
7.1	-	-
7.2	20	1
7.3	-	-
7.4	-	-

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

19

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)	(1,458)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	8,940
8.3	Unused finance facilities available at quarter end (Item 7.5)	19
8.4	Total available funding (Item 8.2 + Item 8.3)	8,959
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	6

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 October 2020

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.