

## QUARTERLY BUSINESS UPDATE

- **Cash position:** Cash balance of \$7.3m as at 30 June 2020
- **Research & Development (R&D) Tax Refund:** R&D tax refund of \$464k
- **Advanced optimisation phase for BARD1-Ovarian:** Pilot v2 RUO BARD1 kits delivered and evaluation at UNIGE commenced
- **Griffith University Agreement:** Consultancy and Commercial Research Agreement executed with Mucosal Immunology Research Group (MIRG) at Griffith University
- **New CSO appointed:** Dr Peter French PhD commences as CSO on 17 August 2020
- **Completion of Sienna acquisition:** Scheme of arrangement implemented and BARD1 acquires Sienna Cancer Diagnostics Ltd (Sienna) post quarter end on 28 July 2020
- **Sienna progress during the quarter:**
  - **hTERT ICC test:** Sienna planned new clinical study strategies with its Advisory Board and expanded its global distribution network
  - **EXO-NET:** Progressed commercial manufacturing of RUO product
  - **SubB2M license:** Sienna executed exclusive licence for pan-cancer marker SubB2M with the potential to revolutionise the cancer diagnostics space
  - **SubB2M assay:** Planning advanced to develop SubB2M assay to underpin future SubB2M-based pipeline development

**Melbourne, Australia, 30 July 2020:** BARD1 Life Sciences Limited (ASX:BD1) (**BARD1** or **Company**), a medical diagnostics company, today released its Appendix 4C and quarterly business update for the quarter ended 30 June 2020.

The financial information below solely relates to the BARD1 entity and not the SDX entity as the merger did not occur until 28 July 2020. However, for fulsome reporting, the activities of SDX for the June quarter have been included in this document.

### FINANCIAL UPDATE

The net cash used in operating activities for the quarter was \$159k. Payments for the quarter included Research and Development (R&D) expenditure of \$212k, patent fees of \$54k, non-R&D staff costs of \$197k, and administration and corporate costs of \$255k. Cash inflows included \$22k in interest, a GST refund of \$23k and a COVID-19 Stimulus payment of \$50k. An R&D Tax Refund of \$464k was also received for the 2019 financial year.

Net cash used in investing activities was \$484k related to advisory costs associated with the proposed merger.

The Company had a closing cash balance at quarter end of \$7.32m on 30 June 2020. This included \$7.0m in term deposits and \$319k in other bank balances.

Payments to related parties of \$125k as per section 6.1 of the Appendix 4C are for director salaries, fees and superannuation contributions.

### RESEARCH AND DEVELOPMENT (R&D) UPDATE

During the quarter, the Company continued to advance the optimisation phase of its BARD1 autoantibody program, whilst Sienna progressed its EXO-NET manufacturing program.

#### BARD1 autoantibody program

BARD1 autoantibody tests measure autoantibodies to variant BARD1 proteins in the blood and use a proprietary cancer-specific algorithm to combine these levels into a cancer score that identifies the presence or absence of a specific cancer.

The Company continued to advance the optimisation phase of its BARD1 autoantibody technology on the Luminex platform with Thermo Fisher Scientific. This is a two-part program to optimise the version 2 (v2)

Research Use Only (RUO) BARD1 kit followed by optimisation of the BARD1-Ovarian test for early detection of ovarian and then other cancers.

The RUO BARD1 kit is a 22-plex peptide panel for detection of human antibodies against BARD1, and is being developed to enable BARD1 to advance the research and commercial development of its BARD1 autoantibody tests for early detection of ovarian, breast and lung cancers on a commercial platform.

During the quarter, Thermo Fisher Scientific completed the optimisation and production of the pilot v2 RUO BARD1 kit for evaluation. In May 2020, the pilot kits were shipped to our collaborator, University of Geneva (UNIGE) and in June 2020 the study protocol was finalised. In July 2020, UNIGE commenced testing under the study to evaluate the reproducibility and accuracy of the new pilot v2 RUO BARD1 kits in previously tested samples of ovarian cancer cases and healthy controls.

Upon successful v2 RUO BARD1 kit evaluation, the Company plans to implement further studies to optimise and validate the BARD1-Ovarian test (peptides and algorithm) for early detection of ovarian cancer in high-risk women with Hereditary Breast and Ovarian Cancer (HBOC) across a range of ovarian cancer types and stages compared to positive and negative controls.

This program is expected to be expanded to evaluate the BARD1-Breast cancer test for early detection of breast cancer in the same population of high-risk women with HBOC across a range of breast cancer types and stages compared to positive and negative controls.

These development activities will be transferred to the Company's Melbourne facility to ensure future product development under its ISO13485 quality management system.

On 2 April 2020, the Company announced formal execution of the Consultancy and Commercial Research Agreement with the Mucosal Immunology Research Group (MIRG) at Griffith University to provide consultancy and scientific services to support the development and commercialisation of the BARD1 technology for detection of ovarian, breast and lung cancer.

### **EXO-NET™ program**

EXO-NET is an exosome capture technology based on the SIEN-NET™ platform with the ability to capture and purify exosomes from patient samples in a scalable, sensitive and specific manner.

Sienna continued to advance the commercial manufacturing of EXO-NET with initial batches of RUO product manufactured in Sienna's US facility and shipped to Australia. This RUO product is being used to support the Company's collaborations with Minomic International for the development of a novel liquid biopsy test for pancreatic cancer, and with VivaZome for the development of an exosome-based therapeutic for Critical Limb Ischaemia (CLI). Both projects have the potential to deliver significant value through future licensing revenues, including possible upfront and milestone payments, in areas where there is a significant need for medical innovation.

### **SubB2M program**

SubB2M is a pan-cancer probe that is specific for cancer cells and has the potential to complement other technologies and biomarkers to detect cancer using a range of testing modalities.

The Company expects to initiate research programs by the end of December 2020 with the objective of building a range of proprietary new SubB2M assays combined with existing and/or novel cancer biomarkers to develop highly specific tests for screening and treatment monitoring of various cancers.

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## **COMMERCIAL UPDATE**

### **hTERT ICC Test**

The hTERT ICC 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.

Sienna recently announced several key marketing initiatives to drive future hTERT revenues. These initiatives included establishment of an Advisory Board and expansion of its global distributor network. The following progress was achieved on these initiatives during the quarter:

1. **Advisory Board:** An Advisory Board was established in the previous quarter with the appointments of Dr Raoul Concepcion and Professor Geoff McCaughan providing expertise in urology and liver cancer, respectively. The Advisory Board has begun planning to undertake additional post-marketing clinical studies, strengthening support for the use of hTERT in bladder cancer diagnosis and driving increased clinician adoption.
2. **Geographic expansion:** New exclusive distributors were appointed in New Zealand, Israel, Sweden and Greece expanding the distributor network for hTERT. The sales and distribution network for hTERT now covers 12 regions globally, with plans to expand into other major marketplaces in Europe and Asia.

The global COVID-19 pandemic has had a significant impact on routine laboratory testing worldwide with laboratory giants such as Quest Diagnostics and Sonic Healthcare reporting a drop in revenues. This reduction in routine laboratory testing includes urine cytology and has negatively impacted short-term demand for the hTERT test. Receipts from customers for the quarter of \$123k were actually higher than the prior quarter (March Quarter: \$94k), however these receipts relate to orders placed in the March quarter.

### **Exclusive Global Licence to SubB2M Cancer Probe**

On 20 April 2020, Sienna executed an exclusive worldwide licence agreement with the University of Adelaide and Griffith University to develop and commercialise a unique cancer probe called SubB2M. The probe binds to a unique sugar molecule only present in human cancers and can detect its presence in the serum of cancer patients. In pilot clinical studies, SubB2M detected cancers with 100% sensitivity and specificity for mid to late-stage cancers and >95% specificity and 100% sensitivity for early-stage breast cancers.

There is also evidence that the cancer-specific sugar is present in a wide range of solid human tumours and can be detected in serum using SubB2M.

Sienna is establishing a collaboration agreement with the Institute for Glycomics at Griffith University to advance the commercial development of SubB2M in an ELISA format assay for the potential early detection of cancer.

### **Industry initiatives: Bridging the gap between Industry and University**

Sienna is working together with the University of Melbourne and Monash University to provide support and scope for industry projects. These projects, run by the universities with support from industry partners, provides final year students with commercial industry projects that reflect real-world technology and business scenarios that can deliver tangible outcomes for the Company and students alike.

The Master of Biotechnology students at Melbourne, led by Sienna's Associate Principal Scientist, Dr Catriona Sinclair, will focus on the SIEN-NET technology, while the final year Global Executive MBA students, led by Sienna's Business Development Manager, Minesh Lalla, will focus on our marketed hTERT product.

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## **CORPORATE UPDATE**

### **Appointment of new CSO**

Post quarter end, on 24 July 2020, BARD1 announced the strengthening of its leadership team with the appointment of Dr Peter French PhD as Chief Scientific Officer (CSO), effective 17 August 2020. Dr French will lead the Company's broader Research and Development (R&D) programs following the acquisition of Sienna Cancer Diagnostics Ltd (Sienna). Dr French will be responsible for creating new intellectual property from the Company's multiple technology platforms, initiating new research projects and collaborations, and advancing its product development programs towards commercial outcomes.

Dr French BSc MSc PhD MBA is a leading biotechnology executive and respected scientist with extensive CSO, CEO and director experience. He has a strong track record in commercialising medical innovations with over 40 years' scientific expertise in cell and molecular biology and over 40 peer reviewed publications across oncology, immunology, microbiology and neuroscience. Most recently, Dr French provided strategic and scientific consulting services to a number of biotechnology companies including Sienna and BARD1. His previous industry roles included being executive director of AusDiagnostics Pty Ltd, Bioxyn

Ltd and BCAL Diagnostics, Managing Director of gene therapy company Benitec Biopharma Ltd, and founder and non-executive director of Cryosite Ltd (ASX:CTE).

### Acquisition of Sienna Cancer Diagnostics

On 8 April 2020, the Company executed a Merger Implementation Agreement with Sienna Cancer Diagnostics Limited (**Sienna**). BARD1 offered 13 BARD1 ordinary shares for every 5 Sienna ordinary shares held by Sienna shareholders. The merger was to occur by way of a Scheme of Arrangement (**Scheme**) requiring both shareholder and court approval.

Post quarter end, on 15 July 2020, Sienna Shareholders approved the Scheme. On 20 July 2020, the Federal Court of Australia approved the Scheme in relation to the proposed acquisition by BARD1 of all the shares in Sienna and the court order was lodged with the Australian Securities and Investments Commission (ASIC), making the Scheme legally effective.

On 28 July 2020, Sienna implemented the Scheme under which Sienna shareholders received 13 new fully paid ordinary shares in BARD1 for every 5 fully paid ordinary shares held in Sienna at 7pm on 23 July 2020. As part of the Scheme, all fully paid ordinary shares in Sienna were transferred to BARD1 and Sienna is now a wholly owned subsidiary of BARD1 and will be removed from the official list of ASX Limited.

On 28 July 2020, Dr Geoff Cumming was appointed Chairman and Helen Fisher as Non-Executive Director of BARD1 Life Sciences, with Peter Gunzburg resigning effective immediately. The Board and Management thank Mr Gunzburg for his leadership and strong support as Chairman. The Company also strengthened its executive leadership team with the appointments of Carl Stubbings as Chief Operations Officer (COO) and Tony Di Pietro as Chief Financial Officer (CFO) and Company Secretary.

The acquisition of Sienna and merger into BARD1 has created a well-capitalised, Australian-based diagnostics company with a high-calibre Board, experienced leadership team and innovative cancer diagnostics portfolio. The Company will focus on delivering novel cancer diagnostics for earlier detection of cancer.

*Authorised for release by joint Company Secretary, Pauline Collinson.*

-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-based medical diagnostics company with an innovative portfolio of diagnostic technologies and products. The Company is focused on the development and commercialisation of best in class lifesaving diagnostic solutions for health care professionals and patients. The cancer diagnostics portfolio includes the marketed hTERT test to aid in the diagnosis of bladder cancer and tests in development for ovarian, breast, lung, prostate and pancreatic cancers. For more information on BARD1, see [www.bard1.com](http://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")**

30JUNE 2020

<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		
1.2 Payments for		
(a) research and development ( <i>including allocated staff costs</i> )	(212)	(817)
(b) patent fees	(54)	(189)
(c) advertising and marketing	0	0
(d) leased assets	0	0
(e) staff costs ( <i>other than R&amp;D staff</i> )	(197)	(712)
(f) administration and corporate costs	(255)	(845)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	22	98
1.5 Interest and other costs of finance paid	0	0
1.6 Income taxes paid	0	0
1.7 Government grants and tax incentives	464	464
1.8 Other ( <i>gst refund and Govt stimulus</i> )	73	112
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(159)</b>	<b>(1,889)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	0	0
(b) businesses	0	0
(c) property, plant and equipment	0	0
(d) investments	0	0
(e) intellectual property	0	0
(f) other non-current assets	0	0

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	0	0
	(b) businesses	0	0
	(c) property, plant and equipment	0	0
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.3	Cash flows from loans to other entities	0	0
2.4	Dividends received (see note 3)	0	0
2.5	Other ( <i>Proposed merger transaction costs</i> )	(484)	(612)
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(484)</b>	<b>(612)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	2,486
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	0	0
3.4	Transaction costs related to issues of equity securities or convertible debt securities	0	(217)
3.5	Proceeds from borrowings	0	0
3.6	Repayment of borrowings	0	0
3.7	Transaction costs related to loans and borrowings	0	0
3.8	Dividends paid	0	0
3.9	Other (provide details if material)	0	0
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>0</b>	<b>2,269</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	7,962	7,551
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(159)	(1,889)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(484)	(612)
4.4	Net cash from capital raising (item 3.10 above)	0	2,269
4.5	Effect of movement in exchange rates on cash held	0	
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>7,319</b>	<b>7,319</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	319	962
5.2	Call deposits	7,000	7,000
5.3	Bank overdrafts	0	0
5.4	Other (provide details)	0	0
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,319</b>	<b>7,962</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
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

125

0

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.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	0	0
7.2 Credit standby arrangements	0	0
7.3 Other (please specify)	0	0
7.4 <b>Total financing facilities</b>	0	0

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

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.

<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)	(159)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	7,319
8.3 Unused finance facilities available at quarter end (Item 7.5)	0
8.4 Total available funding (Item 8.2 + Item 8.3)	7,319
8.5 <b>Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	46.03

*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 2020

Authorised by: By the Board of Directors  
(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.