

Q4 2021 Quarterly Activity Report & Appendix 4C

Key Highlights:

- Successful completion of an initial public offering on the ASX in November 2021, with capital now in place to fund the pivotal study, submission for FDA approval and early commercialisation
- Advanced recruitment for SOLVE pivotal trial, with enrolment expected to complete in H1 2022
- Continued execution of commercial strategy and fostering relationships with US clinical sites, in preparation for FDA approval in H2 2023
- Progressed planning activities for studies in expanded indications: the Totally Leadless CRT (TLC) study and the Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT) study
- Bolstered management team by the appointment of Mr Steve Sandweg as Chief Commercial Officer, Mr Michael Hendrickson as Chief Operating Officer and promotion of Ms Madhuri Bhat to Chief Regulatory Officer
- Appointment of industry experts Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler to the Board of Directors as Independent Non-Executive Directors
- Strong cash position of US\$78.2/A\$107.8¹ million as of 31 December 2021

Sunnyvale, California; 20 January 2022: EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), developer of the world’s only wireless cardiac pacing system for heart failure, is pleased to release its Quarterly Activity Report and Appendix 4C for the December quarter (“Q4 2021”).

EBR Systems’ President & Chief Executive Officer, John McCutcheon said:

“I am excited to share our first quarterly report as an ASX-listed company. EBR is currently in the final stages of enrolment for our SOLVE pivotal trial. We remain on track to complete recruitment during H1 2022 and are targeting FDA submission in H1 2023 for regulatory approval in the US.

The interest and support received during the initial public offering from new and existing investors is an endorsement of EBR System’s WiSE® technology. We made new additions to the Board and management team to help drive our clinical development activities and optimise our commercialisation strategy. The EBR team looks forward to executing near-term milestones and creating value for our shareholders.”

Successful A\$110 million IPO on the ASX

EBR Systems was admitted to the Australian Securities Exchange (ASX) on 24 November 2021 following the successful completion of an initial public offering (“IPO”) that raised approximately A\$110 million. The IPO was supported by institutional and sophisticated investors, including existing Australian shareholders such as M.H. Carnegie & Co, Brandon Capital and superfunds HESTA, Hostplus and Statewide Super, who collectively contributed more than A\$30 million, in addition to a broad range of new institutional and high net worth investors.

Proceeds raised will be primarily used to provide EBR with funding to support its growth strategies, including the clinical development of EBR’s proprietary Wireless Stimulation Endocardially (“WiSE”) device, expanding EBR’s sales and marketing resources and manufacturing capacity, and investment into research and development to improve EBR’s technologies. Funds raised will also support future growth initiatives and fund general working capital requirements.

¹Assumes an A\$:US\$0.726 exchange rate

Clinical Development and Operations Update

The SOLVE pivotal study continues to be a core focus as the Company finalises recruitment in the second, and final phase (single-arm phase) of the trial. The first phase (randomised phase) of the pivotal trial has been completed and following a review of the trial design with the FDA, the study was redesigned as a single-arm, treatment-only phase. The single-arm pivotal study assesses the safety and efficacy of the WiSE System in patients with acute lead failures, chronic lead failures and high-risk upgrades. EBR estimates that these indications have an initial addressable market of US\$2.1 billion in the Company's initial target markets of US, Germany, France, UK, Australia, Benelux and Scandinavia. The primary efficacy endpoint for the trial is a greater than 9.3% improvement in heart function measured by a reduction in left ventricular end systolic volume, and the primary safety performance goal is less than 30% of patients with device or procedure-related complications. These endpoints have been achieved and exceeded in previous clinical studies conducted by EBR including the SOLVE Roll-in study, Select-LV, and the Post Market Surveillance Registry, delineating EBR's history of excellent, reproducible clinical results. Recruitment for final efficacy and interim safety results is scheduled to complete in H1 2022 with headline data expected 7-9 months post enrolment completion. The Company plans to submit a PMA application for U.S. FDA approval in H1 2023. Upon completion of the pivotal trial, EBR also plans to apply for permanent reimbursement for WiSE in France and Germany.

EBR continues to remain focused on completing its clinical trials and is targeting FDA approval in H2 2023. EBR's initial commercial launch will focus on driving adoption of WiSE at key, high-volume, luminary sites within the US followed by select, high-volume outside-of-US sites. Initial adoption will be from sites who have participated in EBR's clinical trials, which is expected to include up to 45 US hospital sites initially. EBR has fostered strong relationships with these sites, all of which are leaders in cardiac medicine, that will assist with promoting and building credibility for WiSE.

Work is also currently underway on two other clinical projects: Totally Leadless CRT (TLC) and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT). TLC will add to EBR's already published experience of pairing the leadless WiSE with a leadless intracardiac pacemaker, which has previously demonstrated strong safety and efficacy results. ACCESS-CRT will evaluate the ability to activate the heart's native conduction system with WiSE. EBR hopes that these prospective, non-randomized studies could lead the way to expanded indications. EBR's estimated market expansion opportunity into new patient groups, indications and geographies is US\$7.1 billion.

Corporate Update

During the quarter, EBR made several additions to the senior management team. This included the appointment of Mr Michael Hendrickson as Chief Operating Officer ("**COO**") and Mr Steve Sandweg as Chief Commercial Officer ("**CCO**") and the promotion of Ms Madhuri Bhat to Chief Regulatory Officer ("**CRO**").

Mr Hendricksen has over 25 years of experience in product development and manufacturing of medical devices and previously served as COO at Ceterix Orthopaedics (Ceterix) where he led the development of the NOVOSTITCH Pro Meniscal Repair System. Mr Sandweg has 30 years of sales and commercialisation experience in Fortune 500 medical technology companies, having recently served as General Manager for Keystone Heart, a Venus Medtech Company. Ms Bhat was promoted to CRO from her previous position as Senior Vice President of Regulatory & Compliance, Quality, and Clinical for EBR. Ms Bhat will be responsible for EBR's global regulatory, compliance, clinical and quality functions.

Prior to listing, EBR welcomed Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler to EBR's Board as Independent Non-Executive Directors. These appointments follow the departures of Mr Dave Stassen and Dr Leighton Reed who have contributed immensely to the EBR's development.

EBR will continue to support clinical sites and patient implants and will continue its ongoing business activities including presentations at high profile cardiology conferences, investor conferences and multiple publications in medical & scientific journals.

Payments made to related parties as described in item 6.1 of the Appendix 4C were for executive director remuneration.

During the quarter, EBR had net cash inflows of US\$73/A\$100.6² million. Net operating cash outflows for the quarter was US\$7.1/A\$9.8² million, mostly relating to clinical and regulatory costs, staff costs, and the prepayment of annual insurance premiums.

Following the IPO, EBR is now well funded to progress its clinical and commercial activities in preparation for US FDA approval in H2 2023.

Use of Funds (Listing Rule 4.7C.2)

In section 8.4 of the Replacement Prospectus dated 28 October 2021 and released on the ASX Market Announcements Platform on 23 November 2021, the Company provided a proposed use of funds statement that is expected to have sufficient working capital to carry out its business objectives as stated below to at least mid-2024. The table below only shows the use of funds from the date of admission to the ASX, 24 November 2021, while the Appendix 4C covers the period 1 October 2021 to 31 December 2021.

Use of Proceeds	Total per the Prospectus (US\$/A\$ ² million)	Actual expenditure 24/11/21 to 31/12/21 (US\$/A\$ ² million)
Capital expenditure towards manufacturing	4.5/6.2	0.0/0.1
Sales and Marketing	19.5/26.8	0.8/1.0
Regulatory and Clinical	14.7/20.3	0.4/0.6
Research and Development	17.4/24.0	0.7/1.0
Costs of the Offer and U.S. Private Placement	5.9/8.1	4.9/6.8
General and Administrative Costs and Working Capital	17.9/24.6	1.9/2.6
Total from proceeds of issue of New Shares	79.9/110.0	8.7/12.1

ENDS

This announcement has been authorised for release by the EBR Systems Finance Disclosure Committee, a committee of the Board of Directors.

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About EBR Systems (ASX: EBR)

Silicon Valley-based EBR Systems (ASX: EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate

² Assumes an A\$:US\$0.726 exchange rate

the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems' WiSE® Technology

EBR Systems' WiSE technology is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart's left ventricle – and the attendant problems – are potentially eliminated. WiSE is an investigational device and is not currently available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control (including but not limited to the COVID-19 pandemic), subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Given the current uncertainties regarding the impact of the COVID-19 on the trading conditions impacting the Company, the financial markets and the health services world-wide, investors are cautioned not to place undue reliance on the current trading outlook.

EBR does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Foreign Ownership Restriction

EBR's CHES Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

EBR Systems, Inc.

ABN

654 147 127

Quarter ended ("current quarter")

December 31, 2021

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	100	537
1.2 Payments for		
(a) research and development	(468)	(1,283)
(b) product manufacturing and operating costs	(1,669)	(7,362)
(c) advertising and marketing	(56)	(170)
(d) leased assets	(136)	(541)
(e) staff costs	(3,074)	(10,883)
(f) administration and corporate costs	(1,797)	(2,064)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	1
1.5 Interest and other costs of finance paid	(51)	(272)
1.6 Income taxes paid	-	0
1.7 Government grants and tax incentives	21	21
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(7,130)	(22,016)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(45)	(911)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 months) US\$'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	5
	(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 (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(45)	(906)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	80,089	80,089
3.2	Proceeds from issue of convertible debt securities	5,715	22,428
3.3	Proceeds from exercise of options	243	839
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4,733)	(5,322)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(600)	(2,400)
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	80,714	95,634

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,214	5,878
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,130)	(22,016)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(45)	(906)

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 months) US\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	80,714	95,634
4.5	Effect of movement in exchange rates on cash held	(501)	(338)
4.6	Cash and cash equivalents at end of period	78,252	78,252

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 US\$'000	Previous quarter US\$'000
5.1	Bank balances	78,252	5,214
5.2	Call deposits	-	-
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)	78,252	5,214

6.	Payments to related parties of the entity and their associates	Current quarter US\$'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	133
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i> Payments represent remuneration paid to executive directors.		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end US\$'000	Amount drawn at quarter end US\$'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
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.		

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(7,130)
8.2	Cash and cash equivalents at quarter end (item 4.6)	78,252
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	78,252
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	11.0
<i>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.</i>		
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:	
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:	
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:	
<i>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.</i>		

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: 20 January 2022

Authorised by: the EBR Systems Finance Disclosure Committee, a committee of the Board of Directors

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.