

#### **ASX ANNOUNCEMENT**

27 April 2022

### Q1 2022 Quarterly Activity Report & Appendix 4C

#### **Key Highlights:**

- Progressed recruitment for the pivotal SOLVE-CRT IDE (SOLVE) clinical trial, with enrolment expected to complete as planned in H1 2022
- Received US FDA (Food & Drug Administration) approval to include leadless pacemakers as a coimplant in the pivotal SOLVE clinical trial
- The opportunity to pair leadless pacemakers with WiSE® expands EBR's initial addressable market by US\$400m, to US\$2.5bn in 2024
- Performed the world's first safe and successful totally leadless Left Bundle Branch Area Pacing (LBBAP) implant of Micra<sup>®</sup> and WiSE<sup>®</sup>, led by Professor Pascal Defaye at the University Hospital of Grenoble, France
- Primary investigators submitted protocols for sponsoring hospital and university approval for the Totally Leadless CRT (TLC) study and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT)
- Presented at the 2022 European Heart Rhythm Association after the quarter
- Strong cash position of US\$70.4/A\$94.11 million as of 31 March 2022

**Sunnyvale, California; 27 April 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 March quarter ("Q1 2022").

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

"This quarter we made lots of progress with our pivotal SOLVE trial, which is on track to complete by the first half of this year. We were pleased to receive FDA approval to include leadless pacemakers as co-implants in the pivotal trial, which expands our patient selection to align with a fast-growing leadless pacemaker market and increases annual initial addressable market opportunity to US\$2.5bn in 2024. In addition to accelerating and expanding our clinical activities, we also focused on commercialisation and business development activities and engaged in discussions with investors, key opinion leaders, expert physicians, and other strategic parties and we will continue to do so. We look forward to this coming quarter and updating shareholders on the exciting developments of the Company."

#### Received FDA approval to include leadless pacemakers in pivotal SOLVE trial

During the quarter, EBR received approval from the US FDA to include commercially available leadless pacemakers as co-implants for the WiSE® CRT System to deliver cardiac resynchronisation therapy (CRT). The pivotal SOLVE trial was originally designed to only include patients with conventional pacemakers (pacemakers with a lead to the right ventricle), however this update expands the patient pool to include patients with a leadless right ventricle pacemaker. WiSE® is the only device that can potentially support the upgrade of patients currently implanted with a leadless right ventricle pacemaker, which solves a significant unmet need by providing a solution to patients with no other upgrade options. The approval indicates that the FDA will consider whether to approve the WiSE® CRT System for use with other leadless pacemakers as an on-label (FDA-approved) treatment option at the time of the Pre-market Approval (PMA) application. If approved, the

<sup>&</sup>lt;sup>1</sup>Assumes an A\$:US\$0.748 exchange rate

opportunity to pair leadless pacemakers with WiSE® expands EBR's initial addressable market by US\$400m (to US\$2.5bn) in 2024, with significant expansion opportunities.

EBR progressed recruitment in the pivotal SOLVE trial which is on track to complete as projected by the H1 2022. The study assesses the safety and efficacy of the WiSE® System in patients with acute lead failures, chronic lead failures and high-risk upgrades, which translates to an initial addressable market of US\$2.5 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 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. The pathway to commercialisation is de-risked, given previous clinical trials of WiSE® have exceeded the efficacy and safety endpoints set for the current pivotal SOLVE trial, and EBR maintains an open dialogue with the FDA.

EBR is targeting FDA approval in H2 2023 with initial commercial launch focusing on the adoption of WiSE® at key, high-volume CRT procedure sites in the US, starting with clinical sites that have participated in EBR's clinical trials. The Company has built an internal direct sales force to execute on its commercialisation plan and drive initial adoption in key target regions.

#### Other clinical activities and opportunities

In April, the world's first totally leadless LBBAP implant of Micra® and WiSE® was performed successfully. The implant has already demonstrated excellent narrowing of the QRS duration, a positive outcome for the patient as this reflects more normal conduction system pacing between the right and left ventricles of the heart. The implant was conducted by Professor Pascal Defaye, a leading cardiologist at the University Hospital of Grenoble, France whose specialities include arrhythmias, atrial fibrillation and device therapy. The implant is a milestone for EBR as it provides validation of EBR's additional clinical projects; the Totally Leadless CRT (TLC) and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT). The implant combines applications of both studies – as it combines WiSE® with a leadless right ventricle pacemaker, and it is also placed in the mid-septal position of the left ventricle of the heart. EBR hopes that these prospective studies could lead the way to expanded indications and WiSE® becoming a denovo (first in line) treatment option for patients with heart failure.

#### Professor Pascal Defaye, Cardiologist at the University Hospital of Grenoble said:

"I am extremely excited to have successfully implanted the world's first totally leadless LBBAP implant with EBR's WiSE® CRT System. I am delighted to see that the treatment has already demonstrated a significant improvement in my patient's condition. WiSE® is at the forefront of innovative technologies in the cardiac rhythm management landscape – this milestone implant represents the beginning of next generation cardiac resynchronisation therapy which will have a huge impact on the lives of many individuals in years to come."

With regards to the TLC and ACCESS-CRT studies, primary investigators have submitted protocols for sponsoring hospital and university approval. The Company remains on track to initiate the two studies, which will be conducted in Australia and Europe, this calendar year.

#### **Corporate Update**

EBR continues to present at high profile cardiology conferences, investor conferences and multiple publications in medical & scientific journals. Subsequent to the quarter, Andrew Shute, EBR's Senior Vice President of Global Field Operations, presented at the 2022 European Heart Rhythm Association. The presentation covered the feasibility of leadless left bundle branch pacing using WiSE® in an animal model. The European Heart Rhythm Association is the leading network of European Cardiac Rhythm Management (CRM) with over 3,500 members around the globe that includes experts and allied professionals in the CRM space.

The Company will also be attending the 2022 Heart Rhythm Society (HRS) Conference in San Francisco which will be held from the 29 April 2022 to 1 May 2022. The HRS is the leading conference on cardiac pacing and

electrophysiology, representing more than 7,000 medical, allied health and science professionals in over 90 countries, specialising in cardiac rhythm disorders.

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

Net operating cash outflows for the quarter was US\$6.8/A\$9.1<sup>2</sup> million, mostly relating to clinical and regulatory costs, staff costs, and the advance purchase of manufacturing materials to prevent supply chain disruption.

EBR is 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 to demonstrate that it 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 January 2022 to 31 March 2022.

Use of Proceeds	Total per the Prospectus (US\$/A\$2 million)	Actual expenditure 24/11/21 to 31/03/22 (US\$/A\$ <sup>2</sup> million)
Capital expenditure towards manufacturing	4.6/6.2	0.1/0.1
Sales and Marketing	20.0/26.8	0.9/1.2
Regulatory and Clinical	15.2/20.3	4.9/6.6
Research and Development	18.0/24.0	1.9/2.5
Costs of the Offer and U.S. Private Placement	6.1/8.1	5.5/7.4
General and Administrative Costs and Working Capital	18.4/24.6	3.3/4.4
Totals	82.3/110.0	16.6/22.0

#### **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

<sup>&</sup>lt;sup>2</sup> Assumes an A\$:US\$0.748 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 CHESS 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

	7
	- 1
EDD Cyclema Inc	- 1
EBR Systems. Inc.	
EBIT Gyotomo, mo.	- 1
	- 1

#### ABN Quarter ended ("current quarter")

654 147 127 March 31, 2022

Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (3 months) US\$'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	351	351
1.2	Payments for		
	(a) research and development	(362)	(362)
	(b) product manufacturing and operating costs	(2,277)	(2,277)
	(c) advertising and marketing	(98)	(98)
	(d) leased assets	(125)	(125)
	(e) staff costs	(3,860)	(3,860)
	(f) administration and corporate costs	(403)	(404)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	4	4
1.5	Interest and other costs of finance paid	(44)	(44)
1.6	Income taxes paid	(2)	(2)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(6,816)	(6,816)

2.	Cas	sh flows from investing activities		
2.1	Pay	ments to acquire or for:		
	(a)	entities	-	-
	(b)	businesses	-	-
	(c)	property, plant and equipment	(48)	(48)
	(d)	investments	-	-
	(e)	intellectual property	-	-

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Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (3 months) US\$'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 (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(48)	(48)

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	209	209
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(566)	(566)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(600)	(600)
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	(957)	(957)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	78,242	78,242
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,816)	(6,816)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(48)	(48)

Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (3 months) US\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(957)	(957)
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
4.6	Cash and cash equivalents at end of period	70,419	70,419

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	70,419	70,419
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)	70,419	70,419

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	53
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.

Payments represent remuneration paid to executive directors.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end 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 qu	arter 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.		itional financing

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(6,816)
8.2	Cash and cash equivalents at quarter end (item 4.6)	70,419
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	70,419
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	10.0
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	n 8.5 as "N/A". Otherwise, a

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:	
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.	

8.6

#### **Compliance statement**

- 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: 27 April 2022

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

#### **Notes**

- 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.
- 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.