ASX ANNOUNCEMENT **26 October 2022**

Q3 2022 Quarterly Activity Report & Appendix 4C

Key Highlights:

- Finalised interim enrolment for the pivotal SOLVE trial, with headline results expected in H1 2023
- Identified the potential for an increased rate of battery depletion, in a small number of devices, caused by the transmitter– affected devices have not impacted patient health or safety to date
    - EBR is working closely with clinical sites and regulatory bodies to provide patient management recommendations and has identified solutions involving manufacturing changes
    - EBR does not expect this development to materially impact data of headline results for pivotal SOLVE trial with final resolution expected prior to PMA submission to the FDA in H2 2023
- Clinical study demonstrating feasibility of WiSE® in Left Bundle Branch Area Pacing published in Heart Rhythm Journal
- EBR holds cash and short-term investments of US$72.3/A$111.4[1] million at 30 September 2022

Sunnyvale, California; 26 October 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 September quarter (**"Q3 2022"**).

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

"Our pivotal SOLVE trial continues to progress following the completion of interim enrolment in June. We remain confident in achieving the primary endpoints with headline results for the trial on track to be released in the first half of 2023. Successful completion of the SOLVE trial continues to be de-risked by previous WiSE® trials and should pave the way for FDA approval and commercialisation.

During the quarter, our ongoing technical assessments identified a transmitter issue affecting a small percentage of WiSE® devices. Our team has already identified a solution and are working diligently to implement it, with no expected impact to previous trial results or timing of the pivotal SOLVE trial.

We remain well funded and do not expect any material changes to our cash requirements as a result of the transmitter issue. We believe that current cash reserves are sufficient to support EBR through its clinical, regulatory, and commercial milestones including FDA approval and initial commercialisation of WiSE® system."

Pivotal SOLVE trial progressing

EBR's pivotal SOLVE-CRT IDE ("SOLVE") trial of WiSE® is underway, following the completed enrolment of 183 patients in June 2022. The SOLVE trial evaluates the safety and efficacy of the WiSE® system in patients with acute lead failures, chronic lead failures, high-risk upgrades and leadless upgrades. With interim patient enrolment complete, EBR expects headline results to be released in H1 2023, following the 6-month follow-up of the last patient.

EBR is targeting pre-market approval (PMA) submission for US Food and Drug Administration (FDA) approval in H2 2023. The SOLVE trial continues to be de-risked, given outcomes from previous clinical trials of WiSE® have exceeded the efficacy and safety endpoints set for the SOLVE trial. Further, EBR is well positioned for commercial success given the FDA granting the Breakthrough Device Designation, which provides access to greater initial payment coverage in the US.

[1] Assumes an A$:US$0.649 exchange rate

EBR estimates an initial annual addressable market of US$2.5bn in 2024, and the Company has a clear and targeted pathway to commercialisation underpinned by successful previous trial results and ongoing engagement with the FDA.

Transmitter issue identified in small percentage of WiSE® devices

Subsequent to the quarter, EBR announced that a potential increased rate of battery depletion caused by the transmitter had been identified in a small percentage of WiSE® devices (announced 21 October 2022). The issue was discovered by EBR's ongoing technical assessments, and the Company has already identified solutions involving manufacturing changes to rectify the issue.

EBR does not expect this issue to impact headline data or timing for the SOLVE trial and remains confident that headline results will be released in H1 2023. The Company expects final PMA submission to the FDA in H2 2023, which will include any changes to design and manufacturing process to resolve the matter.

EBR remains focused on executing its commercialisation strategy and does not expect any material changes to funding requirements to resolve this issue. The Company's existing cash position and access to additional capital (via the Runway Growth Capital debt facility announced in July 2022), provides sufficient balance sheet flexibility to execute on clinical and commercialisation objectives.

Corporate Update

During the quarter, WiSE® technology was featured in a scientific paper published in the leading peer-reviewed journal Heart Rhythm (announced August 2022). The paper, titled "*Feasibility of leadless left ventricular septal pacing with the WISE-CRT system to target the left bundle branch area: a porcine model and multi-centre patient experience"*, generates important insights into feasibility and utility of WiSE® in the treatment of heart failure through left bundle branch pacing. Continuing to feature in reputable publications is an important source of exposure for EBR, while also strengthening the body of data supporting WiSE®.

Net operating cash outflows for the quarter were US$6.7/A$10.3[2] million, mostly relating to clinical and regulatory costs, staff costs, and the advance purchase of manufacturing materials to prevent supply chain disruption.

In addition to its cash balance of US$23.5/A$36.2[2] million on 30 September 2022, EBR held US$48.7m/A$75.0[2] million in short-term investments which will become cash or cash equivalents in the future. Investments are made in fixed income instruments, have a weighted average maturity of 4.5 months, and have a minimum credit rating of A-2/P-2/F2 by at least two of three Nationally Recognised Statistical Rating Organizations, specifically Standard & Poor's, Moody's or Fitch.

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

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 shows the use of funds from the date of admission to the ASX, 24 November 2021, while the Appendix 4C covers the period 1 July 2022 to 30 September 2022.

[2] Assumes an A$:US$0.649 exchange rate

Use of Proceeds	Total per the Prospectus (US$/A$[3] million)	Actual expenditure 24/11/21 to 30/09/2022 (US$/A$[3] million)
Capital expenditure towards manufacturing	4.0/6.2	0.5/0.8
Sales and Marketing	17.4/26.8	1.4/2.2
Regulatory and Clinical	13.2/20.3	14.8/22.8
Research and Development	15.6/24.0	4.0/6.2
Costs of the Offer and U.S. Private Placement	5.3/8.1	5.5/8.5
General and Administrative Costs and Working Capital	16.0/24.6	7.8/12.0
Totals	**71.5/110.0**	**34.0/52.5**

[3] Assumes an A$:US$0.649 exchange rate

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 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	
EBR Systems, Inc.	
ABN	**Quarter ended ("current quarter")**
654 147 127	September 30, 2022

Consolidated statement of cash flows		**Current quarter US$'000**	**Year to date (9 months) US$'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1130	1,896
1.2	Payments for		
	(a) research and development	(378)	(1,166)
	(b) product manufacturing and operating costs	(2,993)	(8,762)
	(c) advertising and marketing	(46)	(367)
	(d) leased assets	(159)	(466)
	(e) staff costs	(3,669)	(11,448)
	(f) administration and corporate costs	(610)	(1,319)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	477	525
1.5	Interest and other costs of finance paid	(433)	(946)
1.6	Income taxes paid	-	(3)
1.7	Government grants and tax incentives	-	8
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(6,681)**	**(22,048)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(243)	(377)
	(d) investments	(48,842)	(48,832)

Consolidated statement of cash flows		Current quarter US$'000	Year to date (9 months) US$'000
	(e) intellectual property	-	-
	(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**	**(49,085)**	**(49,219)**

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	137	387
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(566)
3.5	Proceeds from borrowings	-	20,000
3.6	Repayment of borrowings	-	(2,400)
3.7	Transaction costs related to loans and borrowings	(35)	(794)
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**102**	**16,627**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	79,267	78,242
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,681)	(22,048)

Consolidated statement of cash flows		Current quarter US$'000	Year to date (9 months) US$'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(49,085)	(49,219)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	102	16,627
4.5	Effect of movement in exchange rates on cash held	(55)	(54)
4.6	**Cash and cash equivalents at end of period**	**23,548**	**23,548**

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	23,548	79,267
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)**	**23,548**	**79,267**

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	77
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	50,000	20,000
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	50,000	20,000

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.

On 30 June 2022, the Company entered into a loan and security agreement with Runway Growth Finance Corp, whereby the Company has the availability to borrow up to $50 million US dollars. As of 30 September 2022, the Company has borrowed $20 million US dollars. The Company has not met certain other requirements, which will allow the Company to borrow the remaining $30 million US dollars. The loan accrues interest at the Prime Rate plus 4.90%. Interest is payable on the 15th calendar day of each month, and the loan matures on 15 June 2027.

8.	Estimated cash available for future operating activities	US$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(6,681)
8.2	Cash and cash equivalents at quarter end (item 4.6)	23,548*
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	23,548*

* ***The Company has $48.7m in short-term investments in addition to the $23.5m cash and cash equivalents shown above. With $72.3m in cash and short-term investments, the Company has 10.8 quarters of funding available. Investments are made in fixed income instruments, have a weighted average maturity of 4.5 months, and have a minimum credit rating of A-2/P-2/F2 by at least two of three Nationally Recognised Statistical Rating Organizations, specifically Standard & Poor's, Moody's or Fitch.***

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.5

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

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.

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: 26 October 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.