

# Q2 2023 Quarterly Activity Report & Appendix 4C

## Key Highlights:

- Achieved primary efficacy and safety endpoints in pivotal SOLVE-CRT trial demonstrating clinically significant improvement in heart function and fewer complications compared to benchmarks
- Positive SOLVE-CRT trial results pave the way to FDA approval by the end of 2024, with final PMA submission to the FDA expected in Q1 2024
- Successfully completed a A\$30m capital raise to support regulatory activities and commercial launch
- Unlocked US\$20m from the second tranche of EBR's growth capital facility with Runway Growth Capital
- Strong cash position of ~ US\$84.8 /A\$128.1<sup>1</sup> million as at 30 June 2023, which includes cash and cash equivalents of US\$51.6 /A\$77.8<sup>1</sup> million and short-term investments of US\$33.2 /A\$50.3<sup>1</sup> million

Sunnyvale, California; 25 July 2023: 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 June quarter ("Q2 2023").

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

"We are thrilled with the breakthrough results from our pivotal SOLVE-CRT trial which validates the WiSE CRT device as a safe and effective approach for treating heart failure patients. This landmark achievement is a testament to the hard work of all involved and paves the way forward to FDA approval and initial commercial launch.

We were pleased to announce a capital raising to accelerate our regulatory and commercial objectives, which was well supported by new and existing institutional investors. The capital raising alongside funds received from the second tranche of our growth capital facility, strengthens our balance sheet and provides a strong financial foundation as we enter a new phase of growth. We look forward to advancing towards FDA approval and improving quality of life for patients who have long suffered from heart arrhythmia."

## Positive pivotal SOLVE-CRT trial results

During the quarter, EBR announced positive top-line data from its pivotal SOLVE-CRT trial at the 2023 Heart Rhythm Society ("HRS") Conference in New Orleans. The trial met both primary endpoints, demonstrating that patients implanted with the WiSE CRT device saw a -16.4% reduction in heart volume (compared to -9.3% benchmark) (p = 0.003), with more than 80.9% of patients free from device or procedure-related complications (compared to 70% benchmark) (p < 0.001). The clinically significant outcome builds on previous studies and confirms the WiSE CRT device as a safe, well tolerated, and efficacious CRT treatment.

This positive result represents a major milestone for the Company and validates EBR's technology as a breakthrough in the treatment of cardiac arrhythmia. With top-line results released, EBR will submit a manuscript to a medical journal for peer-review and publication.

## **Clear regulatory pathway**

Given the positive trial results, EBR remains highly focused on progressing its regulatory agenda. The Company aims to finalise its pre-market approval ("PMA") submission to the US Food and Drug Administration ("FDA") in Q1 2024 with full FDA approval expected by the end of 2024. EBR has a successful track record of

<sup>&</sup>lt;sup>1</sup> Assumes an A\$:US\$0.66229 exchange rate

engagement with the FDA spanning multiple years, and the Company looks forward to continuing to engage with the regulatory body during the final stages of the approval process.

Following regulatory approval, EBR's commercialisation strategy will focus on the Company's established partnerships and presence in the US. These relationships have been developed over the course of the SOLVE-CRT trial and will be leveraged to drive initial sales growth with first sales targeted by H1 2025. EBR's pathway to regulatory approval and commercial launch has been significantly de-risked by the positive SOLVE-CRT trial results and the Company looks forward to bringing its ground-breaking technology to patients.

### Successful capital raising

During the quarter, EBR successfully completed a A\$30m placement which was strongly supported by institutional and sophisticated investors. Additionally, EBR launched a Security Purchase Plan ("SPP") for qualified shareholders which closed after the quarter and raised A\$2.7M.

Proceeds from the raise will be used to support EBR's regulatory and commercialisation strategy, including finalising PMA submission to the FDA and executing on initial commercial launch activities including manufacturing scale up and development of sales and marketing capabilities.

### Corporate Update

During the quarter, EBR had net operating cash outflows of US\$7.3 /A\$11.0<sup>2</sup> million, mostly relating to clinical and regulatory costs, staff costs, and ongoing research and development costs.

Following the announcement of positive SOLVE-CRT trial results, EBR unlocked US\$20m from the second tranche of its growth capital facility with Runway Growth Capital.

As of 30 June 2023, EBR holds a cash balance of US\$51.6 /A\$77.8<sup>2</sup> million and US\$33.2 /A\$50.3<sup>2</sup> million in short-term investments which will become cash or cash equivalents in the future. Funds from the second tranche of the placement, SPP and growth capital facility have been received subsequent to the quarter. Investments are made in fixed income instruments, have a weighted average maturity of 4.3 months, and have a minimum credit rating of A-2/P-2/F2 by at least two of three Nationally Recognised Statistical Rating Organisations, specifically Standard & Poor's, Moody's or Fitch.

Payments made to related parties as described in Items 6.1 of the Appendix 4C were for Director renumeration.

## 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 April 2023 to 30 June 2023.

Use of Proceeds	Total per the Prospectus (US\$/A\$ <sup>2</sup> million)	Actual expenditure 24/11/2021 to 30/6/2023 (US\$/A\$ <sup>2</sup> million)
Capital expenditure towards manufacturing	4.1/6.2	0.9/1.4
Sales and Marketing	17.7/26.8	2.0/3.0
Regulatory and Clinical	13.4/20.3	26.5/40.0
Research and Development	15.9/24.0	10.4/15.7

<sup>&</sup>lt;sup>2</sup> Assumes an A\$:US\$0.66229 exchange rate

Costs of the Offer and U.S. Private Placement	5.4/8.1	5.1/7.7
General and Administrative Costs and Working Capital	16.3/24.6	13.1/19.8
Totals	72.8/110.0	58.0/87.6

#### ENDS

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

#### For more information, please contact:

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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, effectiveness 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, 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.

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	30 June 2023	

Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (6 months) US\$'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	113	113
1.2	Payments for		
	(a) research and development	(1,470)	(3,189)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	(1,387)	(3,021)
	(c) advertising and marketing	(163)	(242)
	(d) leased assets	(131)	(263)
	(e) staff costs	(3,565)	(8,135)
	(f) administration and corporate costs	(427)	(686)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	358	682
1.5	Interest and other costs of finance paid	(659)	(1,283)
1.6	Income taxes paid	(1)	(1)
1.7	Government grants and tax incentives		468
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(7,332)	(15,557)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(29)	(176)
	(d) investments	(23,238)	(30,250)
	(e) intellectual property	-	-

Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (6 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	24,587	46,587
	(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	1,320	16,161

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	16,500	16,500
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	12
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(844)	(844)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	20,000	20,000
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	(200)	(200)
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	35,456	35,468

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	22,068	15,456
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,332)	(15,557)

Con	solidated statement of cash flows	Current quarter US\$'000	Year to date (6 months) US\$'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	1,320	16,161
4.4	Net cash from / (used in) financing activities (item 3.10 above)	35,456	35,468
4.5	Effect of movement in exchange rates on cash held	45	29
4.6	Cash and cash equivalents at end of period	51,557	51,557

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	51,557	22,068
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)	51,557	22,068

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	-
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ ation for, such payments.	e a description of, and an
Paym	ents represent remuneration paid to directors.	

7.	<b>Financing facilities</b> 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	40,000	
7.2	Credit standby arrangements	-	-	
7.3	Other (please specify)	-	-	
7.4	Total financing facilities	50,000	40,000	
7.5	Unused financing facilities available at qu	larter 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 \$50m USD. As of 30 June 2023, the Company has borrowed \$40m USD. The Company has not met certain other requirements, which will allow the Company to borrow the remaining \$10m USD. The loan accrues interest at the Prime Rate plus 4.90%. Interest is payable on the 15 <sup>th</sup> 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)	(7,332)
8.2	Cash and cash equivalents at quarter end (item 4.6)	51,557
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	51,557
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.0

The Company has \$33.3m USD in short-term investments in addition to the \$51.6m cash and cash equivalents shown above. With \$84.9m in cash and short-term investments, the Company has 11.6 quarters of funding available. Investments are made in fixed income instruments, have a weighted average effective maturity of 4.3 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.

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?

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?	
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?	
NI/A		1

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: 25 July 2023

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.
- 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.