

Q3 2023 Quarterly Activity Report & Appendix 4C

Key Highlights:

- Reported positive results from SOLVE-CRT randomised sub-analysis, supporting conclusions from the primary study that the WiSE CRT® System is an effective treatment for heart failure patients
- Regulatory activities progressing to schedule, with final PMA submission to the FDA on track for early 2024 and FDA approval by the end of 2024
- Strengthened management team with the appointment of Gary Doherty as Chief Financial Officer
- Featured in the media and at high-profile conferences including the 17th Bioshares Biotech Summit
- Strong cash position of ~ US\$82.4 /A\$128.0¹ million as of 30 September 2023, which includes cash and cash equivalents of US\$44.1 /A\$68.5 million and short-term investments of US\$38.3 /A\$59.5 million

Sunnyvale, California; 23 October 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 September quarter (“Q3 2023”).

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

“We were delighted to report further positive results from our randomised sub-analysis, which strengthen the conclusion from the SOLVE-CRT trial. This further confirms the WiSE CRT System as being clinically safe and effective for treating patients with heart failure.

During the quarter we continued to progress key regulatory and commercialisation activities as we push forwards towards FDA approval and first sales. We also welcomed Mr Gary Doherty (Chief Financial Officer) to the team. He will be pivotal in leading the financial operations of the business as we enter a new phase of growth. We look forward to continuing our engagement with the FDA and remain highly focused on bringing the WiSE CRT System to patients.”

Further positive results from SOLVE-CRT randomised sub-analysis

During the quarter, EBR presented additional clinical data from its SOLVE-CRT trial at the 2023 Asia Pacific Heart Rhythm Society Scientific Session in Hong Kong. A total of 108 participants were enrolled in the randomised phase of the SOLVE-CRT trial, where all participants received the WiSE implant and were randomised in a 1:1 ratio to either the Treatment Group (WiSE system ON) or Control Group (WiSE system OFF).

The Entire Randomised Population contained patients who were previously untreatable, were at high risk of upgrading, and non-responders. The Primary Indications Population contained patients who were previously untreatable and were at high risk of upgrading, but did not include non-responders.

Results from the randomised population Treatment Group demonstrated statistically significant efficacy outcomes with the Treatment Group experienced a 14.6% improvement in heart function (measured by reduction in left ventricular end systolic volume) compared to the Control group, which experienced a 5.2% improvement in heart function. In the Primary Indications Population, patients in the Treatment Group experienced a 18.2% improvement in heart function compared to a 3.1% improvement in heart function for the Control Group.

¹ Assumes an A\$:US\$0.643475 exchange rate

Results of the randomised sub-analysis supports the conclusions of the primary study that the WiSE CRT system is efficacious in treating heart failure patients. With data from the main study and randomised sub-study released, EBR will submit a manuscript to a medical journal for peer-review and publication.

Regulatory and commercialisation activities progressing to schedule

EBR continues to meet regulatory milestones with submission of the fourth module to the FDA as part of the company's phased Pre-market Approval ("PMA") modular approach. The Company remains on track to submit its final module in early 2024, with FDA approval expected late 2024.

The Company is preparing for the initial stages of commercialisation, targeting first sales during H1 2025. EBR's commercialisation strategy focuses on leveraging partnerships with high volume CRT procedure sites in the US and an established specialist sales force to drive initial sales growth. Having recently completed a capital raising and drawdown of the Company's growth capital facility, EBR is fully funded to complete final regulatory processes, scale the business and seize future growth opportunities.

Management team strengthened

During the quarter, EBR appointed Mr Gary Doherty as Chief Financial Officer ("CFO") of the Company, replacing outgoing CFO Frank Hettmann. Mr Doherty brings 30-years of experience in developing high performing finance functions in international medical corporations including his previous role as CFO of Acutus Medical (NASDAQ:AFIB), a medical technology company specialising in cardiac arrhythmia and atrial fibrillation treatment. At Acutus Medical, Mr Doherty led a successful public offering and played a pivotal role in securing distribution agreements with strategic partners. His experience will be vital to EBR, as the Company enters the final stages of its regulatory process with the FDA and readies itself for commercialisation.

Continued media and investor engagement

EBR continues to feature at prominent clinical and investor conferences including the 17th Bioshares Biotech Summit held in Hobart, Tasmania. The Bioshares Biotech Summit is a premier investment forum for Australia's biotech sector, enabling investors and CEOs to meet and gain greater insights.

During the quarter, EBR's management completed an Australian investor roadshow which took place across several states. The roadshow provided shareholders with the opportunity to learn about the Company's recent activities, key milestones and outlook for the year. Attendees were able to receive hands-on experience with EBR's technology and hear directly from a WiSE-CRT patient.

Additionally the company featured in the Device Talks Weekly podcast and the Reach Markets 'Meet the CEO' webinar.

Corporate Update

During the quarter, EBR had net operating cash outflows of US\$7.6 /A\$11.8² million, mostly relating to clinical and regulatory costs, staff costs, the purchase of manufacturing materials, and an increase in interest expense paid.

EBR unlocked and successfully completed the draw down of US\$20m from the second tranche of the Company's growth capital facility with Runway Growth Capital. The second tranche was unlocked following the announcement of positive SOLVE-CRT trial data. EBR also completed its SPP, raising approximately ~A\$2.7m, through the issuance of 2,921,307 new CDIs (equivalent to 2,921,307 shares of common stock).

Funds raised under the SPP and growth facility will be used to support EBR's regulatory and commercialisation strategy, including finalising PMA submission to the FDA, manufacturing scale up, development of sales and marketing capabilities for initial commercial launch, and growth through to H2 2025.

As of 30 September 2023, EBR holds a cash balance of US\$44.1/A\$68.5² million and US\$38.3/A\$59.5² 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 3.8 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

² Assumes an A\$:US\$0.643475 exchange rate

Standard & Poor's, Moody's or Fitch. Funds from the second tranche of the placement, SPP and growth capital facility were received during the quarter.

Payments made to related parties as described in Items 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 2023 to 30 September 2023.

Use of Proceeds	Total per the Prospectus (US\$/A\$ ³ million)	Actual expenditure 24/11/21 to 30/9/2023 (US\$/A\$ ³ million)
Capital expenditure towards manufacturing	4.0/6.2	1.0/1.6
Sales and Marketing	17.2/26.8	2.1/3.3
Regulatory and Clinical	13.1/20.3	30.6/47.6
Research and Development	15.4/24.0	12.2/19.0
Costs of the Offer and U.S. Private Placement	5.2/8.1	5.1/7.9
General and Administrative Costs and Working Capital	15.8/24.6	14.6/22.7
Totals	74.7/110.0	65.6/102.1

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, 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.

³ Assumes an A\$:US\$0.643475 exchange rate

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 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")

30 September 2023

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	(24)	90
1.2 Payments for		
(a) research and development	(1,093)	(4,120)
(b) product manufacturing and operating costs	(1,434)	(3,927)
(c) advertising and marketing	(62)	(276)
(d) leased assets	(91)	(354)
(e) staff costs	(4,104)	(12,240)
(f) administration and corporate costs	(658)	(2,058)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	634	1,316
1.5 Interest and other costs of finance paid	(1,243)	(2,526)
1.6 Income taxes paid	-	(1)
1.7 Government grants and tax incentives	462	929
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(7,613)	(23,167)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(69)	(246)
(d) investments	(9,765)	(40,015)
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (9 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	5,097	51,684
(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	(4,737)	11,423

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	5,115	21,615
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	34	45
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(143)	(987)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	20,000
3.7 Transaction costs related to loans and borrowings	(4)	(204)
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
3.10 Net cash from / (used in) financing activities	5,002	40,469

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	51,557	15,456
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(7,613)	(23,167)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(4,737)	11,423

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (9 months) US\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,002	40,469
4.5	Effect of movement in exchange rates on cash held	(124)	(96)
4.6	Cash and cash equivalents at end of period	44,085	44,085

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	44,085	51,557
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)	44,085	51,557

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	-
<p><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></p> <p>Payments represent remuneration paid to executive directors.</p>		

7.	Financing facilities	Total facility amount at quarter end US\$'000	Amount drawn at quarter end US\$'000
	<i>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.</i>		
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 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.		
	<p>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 September 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 15th calendar day of each month, and the loan matures on 15 June 2027.</p>		

8.	Estimated cash available for future operating activities	US\$'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(7,612)
8.2	Cash and cash equivalents at quarter end (item 4.6)	44,085
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	44,085
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.8
	<p>The Company has \$38.3m USD in short-term investments in addition to the \$44.0m cash and cash equivalents shown above. With \$82.4m 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 effective maturity of 3.8 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.</p> <p><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></p>	
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?

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: 23 October 2023

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.