

Q2 2024 Quarterly Activity Report & Appendix 4C

Key Highlights:

- Regulatory activities progressing to schedule as EBR remains on track to submit the final module of its Pre-Market Approval (“PMA”) Application to the U.S. Food and Drug Administration (“FDA”) in Q3 2024
- Appointed Mr Erik Strandberg as Chief Commercial Officer, bringing extensive commercial cardiovascular leadership experience to drive EBR’s US commercialisation strategy
- Commercial readiness activities currently underway, including fostering relationships with key US clinical sites in preparation for FDA approval targeted in Q1 2025
- Presented WiSE[®] and EBR’s positive SOLVE-CRT study results at key US and European conferences
- EBR holds cash and short-term investments of US\$54.1/A\$81.1¹ million as of 30 June 2024

Sunnyvale, California; 26 July 2024: EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), developer of the world’s only wireless cardiac pacing device for heart failure, is pleased to release its Quarterly Activity Report and Appendix 4C for the June quarter (“Q2 2024”).

Continued progress in regulatory and commercial readiness activities

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

“We continued to make important progress toward our final PMA submission in Q3 2024, underpinned by our positive engagement with the FDA. During the quarter we welcomed Erik, whose track record in driving growth in the medical device industry will push us towards fully realising the commercial potential of WiSE in the U.S. Our WiSE-CRT System continues to receive significant attention at key industry conferences, providing the opportunity to showcase our technology to peers and the scientific community. We look forward to this coming quarter and updating shareholders on more exciting developments by the Company.”

EBR continues to advance its regulatory and commercialisation programme and intends to submit the final module of its PMA application to the FDA in Q3 2024. EBR is confident in achieving its submission target which is supported by the Company’s Breakthrough Device Designation and its direct and positive communication channel with the FDA.

During the quarter, EBR appointed Mr. Erik Strandberg as Chief Commercial Officer to focus on leading the company’s US commercialisation strategy. Mr Strandberg brings over two decades of medical device sales experience, having held senior leadership roles at AtriCure, Boston Scientific, St Jude Medical, and Guidant Corporation. Mr Strandberg’s robust experience and strategic acumen positions him exceptionally to drive EBR’s upcoming growth initiatives.

To drive initial sales, EBR will leverage its partnerships with high volume CRT procedure sites developed over the course of its SOLVE-CRT trial – targeting four specific patient groups within the US market (e.g. acute lead failure, high risk upgrades, leadless upgrades, and chronic lead failure patients). With EBR’s Breakthrough Device Designation, the Company automatically qualifies for the New Technology Add-On Payment (“NTAP”) and Transition Pass-Through (“TPT”) reimbursement programs, allowing EBR to set an average selling price (“ASP”) of ~US\$45k upon commercialisation.

¹ Assumes an A\$:US\$0.667 exchange rate

Active media and investor engagement

EBR continues to present at clinical and investor conferences. Subsequent to the quarter, EBR's management team attended the 18th Bioshares Biotech Summit held in Fremantle, Western Australia. The Bioshares Biotech Summit is a high-profile investment conference for Australia's biotech sector, enabling investors to gain greater insights.

Corporate Update

EBR released its 2023 Annual Report on 30 April 2024 and held its Annual Meeting of Stockholders on 30 May 2024. All resolutions were decided and passed by way of poll. The results of the meeting are set out in the announcement titled 'Results of 2024 Annual Meeting of Stockholders', released on 30 May 2024.

During the quarter, EBR had net operating cash outflows of US\$10.3/A\$15.5² million, mostly relating staff costs, clinical and regulatory costs, general and administrative expenses, and interest expense. Payments made to related parties as described in Items 6.1 of the Appendix 4C were for Executive and Non-Executive Director remuneration.

In addition to its cash balance of US\$8.4/A\$12.6² million on 30 June 2024, EBR held US\$45.7/A\$68.5² 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 4.1 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.

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.

EBR Systems' WiSE Technology

² Assumes an A\$:US\$0.667 exchange rate

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 Depository 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 June 2024

Consolidated 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	10	33
1.2 Payments for		
(a) research and development	(2,771)	(5,285)
(b) product manufacturing and operating costs	(76)	(570)
(c) advertising and marketing	(75)	(161)
(d) leased assets	(112)	(215)
(e) staff costs	(4,474)	(10,077)
(f) administration and corporate costs	(1,860)	(2,264)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	400	643
1.5 Interest and other costs of finance paid	(1,369)	(2,729)
1.6 Income taxes paid	-	(2)
1.7 Government grants and tax incentives	-	322
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(10,327)	(20,305)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant, and equipment	(83)	(157)
(d) investments	(11,102)	(19,980)
(e) intellectual property	-	-

Consolidated 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	22,141	34,126
	(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	10,956	13,989

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	2	113
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
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	2	113

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,726	14,579
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,327)	(20,305)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	10,956	13,989

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (6 months) US\$'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2	113
4.5	Effect of movement in exchange rates on cash held	7	(12)
4.6	Cash and cash equivalents at end of period	8,364	8,364

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	8,364	7,726
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)	8,364	7,726

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	96
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 the Executive Chairman and Non-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.</i>		
<i>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 June 2024, 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)	(10,327)
8.2 Cash and cash equivalents at quarter end (item 4.6)	8,364
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	8,364
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.81
<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?
	<p>The Company has \$45.7m USD in short-term investments in addition to the \$8.4m cash and cash equivalents shown above. With \$54.1m in cash and short-term investments, the Company has 5.2 quarters of funding available. Investments are made in fixed income instruments, have a weighted average effective maturity of 4.1 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>

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?

No additional steps deemed necessary, as the Company has \$54.1m USD available to fund operations, as discussed in section 8.6.1 above.

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?

The Company expects to be able to continue operations based on the availability of cash and short-term investments, as discussed in section 8.6.1 above.

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 July 2024

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 – e.g. 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.