

ASX ANNOUNCEMENT

30 January 2023

Q4 2022 Quarterly Activity Report & Appendix 4C**Key Highlights:**

- Pivotal SOLVE-CRT (“SOLVE”) trial progressing according to schedule, with headline results on track to be released in H1 2023
- EBR continues to feature in the media and at leading global conferences including the 15th APHRS Scientific Session, where five abstracts featuring WiSE[®] technology were presented
- Investigation into WiSE device transmitter proceeding in line with timing expectations, with no impact expected to timing or headline data for the pivotal SOLVE trial
 - Remain on track to resolve issue prior to final PMAA submission to the FDA in H2 2023
- EBR holds cash and short-term investments of US\$64.5/A\$94.8¹ million at 31 December 2022

Sunnyvale, California; 30 January 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 December quarter (“Q4 2022”).

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

“We are pleased to report that our pivotal SOLVE trial continues to progress, and we remain confident in achieving the primary endpoints. We are looking forward to announcing the headline results in the first half of 2023.

Our WiSE technology continues to feature in leading conferences around the world, further strengthening the body of data supporting WiSE while promoting our technology to a wide audience, including industry partners and the broader scientific community.

We are working diligently to rectify the transmitter issue announced during the quarter, with design and manufacturing changes to be implemented prior to PMAA submission, paving the pathway for FDA approval and commercialisation.

Pivotal SOLVE trial underway

EBR’s pivotal SOLVE trial of WiSE continued to progress following the completed enrolment of 183 patients in June 2022. With the final 6-month follow-up expected to occur in Q1 2023, the Company remains confident that it will achieve the 6-month primary endpoints and looks forward to sharing headline results in H1 2023. Successfully achieving the SOLVE clinical endpoints is a major milestone towards obtaining pre-market approval (“PMA”) from the US Food and Drug Administration (“FDA”). EBR aims to submit this application in H2 2023.

Following FDA approval, EBR plans to initially target high-volume CRT procedure sites in the US, starting with those that have previously participated in the WiSE clinical trials. The Company estimates an initial annual addressable market of US\$2.5bn in 2024 and has de-risked the pathway to commercialisation via Breakthrough Device Designation, which provides access to greater initial payment coverage in the US, and ongoing engagement with relevant regulatory bodies.

WiSE technology featured in global conference

¹ Assumes an A\$:US\$0.6805 exchange rate

During the quarter, EBR's WiSE technology was featured at the 15th Asia Pacific Heart Rhythm Society (APHRS) Scientific Session in Singapore. The APHRS is a leading non-profit organisation that represents medical, allied health, and science professionals specialising in cardiac rhythm disorders in the Asia-Pacific region. The annual conference is a premier event featuring industry workshops and a core scientific programme delivered by international and regional speakers. Five abstracts featuring WiSE were accepted for presentations, highlighting the technology's position at the forefront of innovation in the cardiac rhythm management landscape.

Solution to transmitter issue expected prior to PMAA submission in H2 2023

During the quarter, EBR announced that a subset of WiSE transmitters were causing the battery to deplete faster than usual. As announced in October, the Company has a solution that it is diligently working to implement.

EBR does not expect any impact to the headline data or timing of the SOLVE trial and the Company remains confident that the required changes to design and manufacturing processes will be made prior to PMAA submission to the FDA in H2 2023.

Corporate Update

Net operating cash outflows for the quarter were US\$7.9/A\$11.7² million, mostly relating to clinical and regulatory costs, staff costs, the purchase of manufacturing materials, and the prepayment of annual insurance premiums.

In addition to its cash balance of US\$15.5/A\$22.7² million on 31 December 2022, EBR held US\$49.0m/A\$72.1² 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 3.6 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.

There were no payments made to related parties.

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 October 2022 to 31 December 2022.

Use of Proceeds	Total per the Prospectus (US\$/A\$² million)	Actual expenditure 24/11/21 to 31/12/2022 (US\$/A\$² million)
Capital expenditure towards manufacturing	4.2/6.2	0.8/1.2
Sales and Marketing	18.2/26.8	1.6/2.4
Regulatory and Clinical	13.8/20.3	18.7/27.5
Research and Development	16.3/24.0	5.2/7.6
Costs of the Offer and U.S. Private Placement	5.5/8.1	5.1/7.5
General and Administrative Costs and Working Capital	16.7/24.6	10.8/15.9
Totals	74.7/110.0	42.2/61.1

² Assumes an A\$:US\$0.6805 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, 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 (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 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")

December 31, 2022

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
1. Cash flows from operating activities		
1.1 Receipts from customers	25	1,921
1.2 Payments for		
(a) research and development	(448)	(1,581)
(b) product manufacturing and operating costs	(1,923)	(10,685)
(c) advertising and marketing	(52)	(419)
(d) leased assets	(147)	(613)
(e) staff costs	(3,447)	(14,895)
(f) administration and corporate costs	(1,405)	(3,157)*
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	19	544
1.5 Interest and other costs of finance paid	(556)	(1,502)
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	(7,934)	(30,382)

* The Company has increased administrative and corporate costs \$433k USD for expenses that were inadvertently included as transactions costs related to the issuance of equity securities on the Appendix 4C for the quarter ended March 31, 2022. See section 3.4 below.

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-

Consolidated statement of cash flows	Current quarter US\$'000	Year to date (12 months) US\$'000
(c) property, plant and equipment	(320)	(730)
(d) investments	(1,776)	(50,618)
(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	2,000	2,000
(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	(96)	(49,348)

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	35	422
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(80)	(213)*
3.5 Proceeds from borrowings	-	20,000
3.6 Repayment of borrowings	-	(2,400)
3.7 Transaction costs related to loans and borrowings	-	(794)
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
3.10 Net cash from / (used in) financing activities	(45)	17,015

* The Company has decreased transaction costs related to the issuance of equity securities corporate costs \$433k USD for expenses that were inadvertently misclassified on the Appendix 4C for the quarter ended March 31, 2022. See section 1.2(f) above.

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter US\$'000	Year to date (12 months) US\$'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	23,548	78,242
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,934)	(30,382)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(96)	(49,348)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(45)	17,015
4.5	Effect of movement in exchange rates on cash held	(17)	(71)
4.6	Cash and cash equivalents at end of period	15,456	15,456

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	15,456	15,456
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)	15,456	15,456

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	-
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 <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>	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.		
<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 31 December 2022, the Company has borrowed \$20m USD. The Company has not met certain other requirements, which will allow the Company to borrow the remaining \$30m 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)	(7,934)
8.2 Cash and cash equivalents at quarter end (item 4.6)	15,456
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	15,456
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.9
<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 \$49.0m USD in short-term investments in addition to the \$15.5m cash and cash equivalents shown above. With \$64.5m in cash and short-term investments, the Company has 8 quarters of funding available. Investments are made in fixed income instruments, have a weighted average maturity of 3.6 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?	
<p>No additional steps deemed necessary, as the Company has \$64.5m USD available to fund operations, as discussed in section 8.6.1 above.</p>	

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: 30 January 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.