

EBR Systems, Inc

Better pacemaking = better patients

EBR Systems, Inc (ASX:EBR) listed on the ASX in November 2021, raising \$110m. The company is developing and commercialising a wireless cardiac pacing system for the left ventricle of the heart. EBR's patented Wireless Stimulation Endocardially (WiSE) device is currently the only wireless solution for left ventricle pacing that can be used for cardiac resynchronisation therapy (CRT). Founded in 2003 and based in California, EBR holds 53 US patents and 44 corresponding international patents relating to implantation and wireless powering of an electrode. EBR's technology can be used in conjunction with other leading device providers to deliver effective CRT for patients where wired electrodes fail. The company has strong institutional shareholder backing with IPO proceeds to be used to support clinical development of the WiSE device followed by investment in sales and marketing and further R&D aimed at commercialisation of the device from 2023 with US FDA approval targeted for H2 2023. EBR remains focused on successful completion of current clinical trials which are also expected to ultimately lead to adoption of WiSE at key hospital sites within the US followed by select sites outside the US. The company has continued to strengthen its team adding a Chief Operating Officer, Chief Commercial Officer and Chief Regulatory Officer in Q4 FY22.

Business model

EBR is engaged in development and commercialisation of the WiSE device through completion of current clinical trials and expected regulatory approvals in the US and subsequently in Europe and elsewhere. Following forecast US FDA approval in 2023 the company expects to commence sales to high-visibility sites in the US (which have participated in trials) followed by select sites elsewhere.

Q2 result highlights EBR is on-track

The company's recent IPO leaves an estimated 11 quarters of funding available to pursue EBR's development and commercialisation agenda. The company is conducting one and planning two additional clinical trials of the WiSE CRT device which are expected to further substantiate the benefits of the strategy. Once the high-need patient market (estimated at US\$2.1b) has been addressed the company intends to expand usage in other patient groups, potentially expanding market size to US\$7.1b in the US.

Look to peers aimed at the US market

Australian listed medical device companies with comparable businesses include Resmed (ASX:RMD), Cochlear (ASX:COH) and Impedimed (ASX:IPD). However, these examples have relatively mature devices and businesses. We were unable to identify a directly comparable implanted device company listed on the ASX but companies manufacturing medical devices aimed at the US market included Pro Medicus (ASX:PME), 4D Medical (ASX:4DX) and CardieX (ASX:CDX). EBR remains in an early stage of development and consequently has reported no revenue and a large EBITDA loss. Valuations should be focused on the relative size of the addressable markets and potential revenues.

Historical earnings and ratios (In US\$m unless otherwise stated)

| Year end | Revenue | EBITDA Adj.* | NPAT Adj. | NPAT Rep. | EPS Adj. (c) | EPS Rep. (c) |
|----------|---------|--------------|-----------|-----------|--------------|--------------|
| 12/19a | 1.29 | (25.18) | (26.27) | (24.81) | n.a | n.a |
| 12/20a | 0.00 | (20.33) | (27.10) | (25.72) | (2.05) | (1.95) |
| 12/21a | 0.00 | (21.41) | (39.27) | (39.34) | (0.93) | (0.95) |

Source: Company data; *EBITDA, NPAT and EPS adjusted for one-time, non-cash items ^calculated using current enterprise value

Health Care Equipment and Services

11th March 2022

Share Details

| | |
|-------------------------|-----------|
| ASX code | EBR |
| Share price | \$0.65 |
| Market capitalisation | \$174.2M |
| Shares on issue | 268M |
| Net cash at 31-Dec-2021 | US\$78.3M |
| Free float | 81% |

Share Performance (since listing)



Upside Case

- Expected results affirmation by SOLVE trial
- Regulatory approval on-track
- Expansion to first-line CRT treatment option

Downside Case

- Poor result from SOLVE trial
- US FDA and Australian TGA approval delayed
- Alternative technologies emerge

Catalysts

- SOLVE trial headline results H2 2022
- US FDA PMA submission H1 2023

Comparable Companies (Aust/NZ)

Resmed (ASX:RMD), Cochlear (ASX:COH), Pro Medicus (ASX:PME), 4D Medical (ASX:4DX)

Board and Management

| | |
|---------------------|------------------------|
| Allan Will | Executive Chair |
| John McCutcheon | President and CEO |
| Dr Christopher Nave | Non-Executive Director |
| Trevor Moody | Non-Executive Director |
| Dr Bronwyn Evans | Non-Executive Director |
| Dr David Steinhaus | Non-Executive Director |
| Karen Drexler | Non-Executive Director |

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FINANCIAL SERVICES GUIDE

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AFSL 456663

Effective Date: 6th May 2021



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- our services
- how we transact with you
- how we are paid, and
- complaint processes

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Website: www.afca.org.au; Email: info@afca.org.au; Telephone: 1800931678 (free call)

In writing to: Australian Financial Complaints Authority, GPO Box 3, Melbourne, VIC, 3001.

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