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EBR Systems Inc: Wise Pivotal Heart Trial 'Efficacy, Safety'

EBR SYSTEMS INC

EBR says that its 183-patient Wise device pivotal trial met both the primary efficacy and safety endpoints with statistically significant improvement against pre-set benchmarks.

EBR said the 'Solve-CRT' (cardiac re-synchronization therapy) trial's efficacy endpoint for the wireless stimulation endocardially, or Wise device, was the improvement in heart function measured by reduction in left ventricular end systolic volume (LVESV) and showed a reduction of 16.4 percent using its Wise system compared to a performance goal of a reduction of 9.3 percent ($p = 0.003$).

The company said safety, measured by freedom from a device, or procedure-related complications, was 80.9 percent compared to a goal of 70 percent ($p < 0.001$).

EBR said it planned to file a pre-market approval submission to the US Food and Drug Administration by April 2024.

In a webinar, EBR chief executive officer John McCutcheon said the trial data was "the most successful milestone in the company's history".

He said that the trial population was that group of heart patients who had already failed cardiac re-synchronization therapy (CRT).

"Wise is complementary. There is no competition," Mr McCutcheon said.

"We are in a free space. These are patients that don't have any other options," Mr McCutcheon said.

Mr McCutcheon said the binary risk was the study data and “we have crossed that binary risk”, there was nothing controversial in the data and with breakthrough device status, he expected an FDA response on Wise in six to nine-months from filing the final module.

The webinar slides said that all the data analyzed to date had shown “consistent, positive results in reversing heart failure symptoms and physiology”.

Mr McCutcheon said that with heart failure patients the QRS section of their electro-cardio-gram widened showed a slowing of the electrical signal, and the trial showed a 39 milli-second shortening of that time, which was an improvement.

Mr McCutcheon said that following the positive trial results the company would be able to draw a further $US20 million ($A30.1 million) from Runway Growth Finance, next month Last year, EBR said the loan, financed by Chicago’s Runway Growth Finance Corp, had a term of five years, and a floating rate with a floor of 4.9 percent (BD: Jul 1, 2022).

“We drew $US20 million at that time and the $US20 million second tranche was contingent upon meeting the primary endpoints,” Mr McCutcheon said.

“The last $US10 million is contingent on FDA approval, but expires June 2024,” Mr McCutcheon said. “We may not be able to draw that final tranche,” he said.

EBR was up 9.5 cents or 10.5 percent to $1.00 with 2.65 million shares traded.