



**ASX: HWH RELEASE**

**6 SEPTEMBER, 2021**

**CLINICAL TRIAL USING ECHOiQ'S NEW  
CARDIO-DIAGNOSTIC AI TECHNOLOGY  
TO BE FUNDED BY GLOBAL INDUSTRY LEADER  
EDWARDS LIFESCIENCES (NYSE:EW \$US74 billion Mkt Cap)**

**Highlights**

- **Fully funded clinical trial - Houston We Have announces funding by global leader in replacement heart valves Edwards Lifesciences (NYSE:EW \$US74 billion Mkt Cap) for clinical trial of ECHOiQ's technology**
- **Pioneering study - Trial to be conducted in partnership with the National Echo Database of Australia (NEDA) to confirm the performance of ECHOiQ's Enhanced Screening Program in detecting at-risk patients with severe aortic stenosis**
- **Appointment of regulatory consultants – The company has appointed expert MedTech regulatory consultants as it commences process for FDA approval of clinical applications of its technology**
- **Patent Pending – Applications for patents in several key markets are being pursued for ECHOiQ's AI technology**

**Sydney:** Predictive analytics and Artificial Intelligence company Houston We Have (the Company) (ASX:HWH) is pleased to announce significant progress has been achieved with a fully funded clinical trial to confirm the performance of ECHOiQ's artificial intelligence (AI) based Enhanced Screening Program (ESP) in detecting the at-risk phenotype of severe aortic stenosis (AS) in real-world patient datasets.

**ECHOiQ background**

The Company recently completed the acquisition of ECHOiQ (refer ASX announcement released 15 July 2021). ECHOiQ uses a range of echocardiographic measurements and applies a combination of machine learning and current medical guideline recommendations to provide a

probability of the phenotype of severe aortic stenosis – the most common form of heart valve disease.

Unlike traditional diagnosis protocols, ECHOiQ's ESP does not rely on left ventricular outflow tract (LVOT) obstruction measurement, but instead enhances clinical detection of severe aortic stenosis and additional patients exhibiting similar features to those with severe AS.

There is an increasing body of research that indicates significant numbers of patients with treatable forms of heart valve disease are being missed by current diagnosis protocols. In a Baker Institute white paper<sup>1</sup> released to the Australian Federal government on 10 August 2021, it is indicated that of the ~500k Australians living with heart valve disease, half of them are unaware of their condition. Many forms of heart valve disease are highly treatable with minimally invasive and economically viable methods which require little in the way of recovery times. The ECHOiQ technology is expected to support better diagnosis of potential valve replacement patients.

### **ECHOiQ Clinical Trial**

In a significant step forward ECHOiQ will be partnering with the National Echo Database of Australia (NEDA) and Edwards LifeSciences in a clinical trial to be fully funded by Edwards LifeSciences to confirm the performance of ECHOiQ's AI based ESP technology. There are two primary objectives of the trial:

1. To evaluate the performance of ECHOiQ's AI based ESP technology in identifying patients with aortic stenosis in de-novo echocardiographic databases who are 'at-risk' of mortality.
2. To determine the number and proportion of additional patients, compared to standard clinical image evaluation, that might benefit from being identified as 'at-risk' of mortality when ECHOiQ's ESP is applied.

The clinical trial will provide the opportunity to not only demonstrate the performance of ECHOiQ's AI-based ESP in identifying AS patients who are 'at-risk' of mortality, but also will provide the opportunity to identify the potential for under-diagnosis of 'at-risk' patients with severe AS using the current standard diagnosis protocols. The ECHOiQ risk prediction phenotype includes patients with moderate aortic stenosis – individuals who might traditionally not have been identified for further consideration using established guidelines.

The clinical trial will be conducted at hospitals located in Australia and will commence subject to governance approvals at the relevant institutions. The trial will be conducted with clearly defined protocols, including primary and secondary objectives. This is a retrospective observational and evaluation study.

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<sup>1</sup> <https://www.baker.edu.au/impact/advocacy/valve-disease>

Importantly, in order to conduct the clinical trial, ECHOiQ has exclusive access to the NEDA database, which is the world's largest source of measurement data acquired from Echocardiograms linked to outcomes. ECHOiQ has entered into a Licence Agreement with NEDA whereby NEDA has granted ECHOiQ an exclusive licence to access and use the database owned by NEDA, the largest of its kind worldwide.

The clinical trial is being fully funded by Edwards Lifesciences (NYSE:EW). Edwards Lifesciences is the world's largest manufacturer of replacement aortic valves used in transcatheter aortic valve implantation (TAVI) and surgical aortic valve implantation (SAVI) therapies.

### **IP & Regulatory update**

In conjunction with the clinical audit, the Company continues to progress the near-term commercialisation opportunities for ECHOiQ and is pleased to announce it has appointed a leading United States (US) MedTech consultancy to advise and support the Company in its US FDA and other associated regulatory applications for ECHOiQ's technology. The US is a significant target market for the Company, obtaining FDA approval as soon as possible is of key importance. FDA approval is required to ensure the safety and effectiveness of any technology or software that is applied alongside medical devices used in the delivery of healthcare. CE applications, required in markets such as Canada and Europe are expected to follow.

The Company has also recently appointed a patent attorney to protect ECHOiQ's intellectual property and is in the process of seeking an application for protection for its distinctive and unique algorithm. Trademark protection is also being sought for a number of naming conventions associated with the Company's technology.

### **Key market opportunities**

The Company has identified a number of clear industry segments to pursue commercial opportunities for ECHOiQ. Valve manufacturers, hardware producers of Echo machines and reporting software, specialist cardiologists/clinics, hospitals, the health insurance sector and general practitioners are all large target market opportunities. For the short term, the Company is focused on commercial development opportunities with Valve manufacturers and hardware producers of Echo machines, and has commenced strategic engagement with globally recognised leaders, like Edwards Lifesciences, in these industry segments. In the longer term, ECHOiQ is examining the application of its AI technology approach to other forms of cardiac and structural heart disease.

### **Houston We Have Chairman Andrew Grover said:**

*"The clinical trial for ECHOiQ's ESP technology is a key step in validating and confirming the performance of our unique AI which has the potential to improve patient outcomes in one of the world's largest health markets – cardiovascular disease. Funding the trial is the world's leading manufacturer of replacement aortic valves, an industry sector which is a key focus for the Company. The trial will be conducted in partnership with NEDA through whom we have proprietary access to one of the world's*

*largest datasets of echocardiograms. This access means we are able to develop enhanced algorithms and diagnostic capability across a number of cardiology related indications where we believe we have the potential to significantly improve the effectiveness of traditional diagnosis protocols.”*

**-ENDS-**

Authorised for release by the Board of Directors of Houston We Have Ltd

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**ABOUT**

Houston We Have (ASX: HWH) uses patented augmented intelligence software, data science and commercial insight to help organizations make better decisions, at speed and without bias. The company develops automated technology solutions that can be deployed in various industries and contexts. It specializes in harnessing the power of data and human inputs to predict outcomes and associated degrees of certainty. Houston We Have is headquartered in Sydney, Australia with employees in Australia, New Zealand and the UK. More information is available at [www.houstonwehave.ai](http://www.houstonwehave.ai).