

ECHO IQ COMMENCES NEW HEART FAILURE CLINICAL STUDY USING AI

Highlights:

- Echo IQ has developed a novel Artificial Intelligence (“AI”) algorithm for the detection of heart failure
- Agreement with leading Australian research group St. Vincent’s Institute of Medical Research to advance a clinical study using new AI solution to detect risk of heart failure
- Clinical study underway following successful internal validation
- Heart failure is the world’s leading cause of hospitalisation in people over 65, and re-hospitalisation overall (accounting for 17% ⁽¹⁾ of US healthcare expenditure)
- New solution expected to improve health and economic outcomes in a US\$60bn (per annum) healthcare market
- FDA application to be made upon completion of clinical studies
- Appointment of leading US reimbursement advisors to maximise commercial applications
- Comparable reimbursement rates of US\$284 (CPT) and US\$1023 (NTAP) per assessment and an applicable potential US market of up to 7,000,000 echocardiograms per annum
- Multiple commercial applications to be explored including licencing to hospital groups and treatment providers

Sydney: Artificial Intelligence and Medical Technology company Echo IQ (“the Company”) (ASX: EIQ) is pleased to report that it has entered into an agreement with leading Australian research institute, St. Vincent’s Institute of Medical Research (“SVI”), to undertake a new clinical study to establish the operational characteristics of a novel AI-backed solution for heart failure.

Echo IQ Chairman, Andrew Grover said: *“This agreement and clinical study with St. Vincent’s Institute considerably broadens the Company’s commercial opportunity and we are extremely excited by the clinical and commercial applications for this innovative new solution.*

Heart failure is a significant health issue, with more than 50% of sufferers currently dying within 3-4 years. Given the seriousness of this condition and its impact on hospital readmission rates, we are pursuing a clear pathway to obtain insurance reimbursement codes for this solution as a priority.

We look forward to updating shareholders of our progress in due course.”

Heart Failure Background

Echo IQ has developed a novel AI algorithm for the automatic detection of heart failure. This life-threatening condition occurs when the heart is unable to meet the blood flow requirements of the body. Some forms of heart failure are notoriously difficult to diagnose despite established guidelines. Symptoms can include breathlessness, leg swelling and fatigue. Treatment for heart failure has a significant impact on survival, hence making an accurate diagnosis is of great importance. The Company expects its AI-backed solution may assist in the early detection of the condition and improve a doctor's potential to expedite recommended treatments which include medication and general lifestyle improvements.

In Australia, heart failure affects over half a million individuals⁽²⁾ representing more than 150,000⁽³⁾ hospitalisations per year, over 60,000 deaths, and a cost of over \$3 billion⁽⁴⁾. Globally, heart failure affects more than 60 million people⁽⁵⁾ and is the world's leading cause of hospitalisation in older individuals over 65 years old, accounting for 17% ⁽⁶⁾ of all US healthcare expenditure. Reducing the social and economic burden of this condition is regarded as a major global public health priority.

Echo IQ's AI Solution

As previously advised, Echo IQ has successfully developed proprietary AI-backed technology to address earlier and more accurate identification of risk for aortic stenosis, a leading form of heart valve disease.

The Company's novel algorithm for heart failure leverages its exclusive access to the world-leading NEDA (National Echo Database of Australia) database of echocardiographic records. This completely new algorithm reliably identifies the heart failure phenotype even when important information was not measured during the echo examination, in contrast to current diagnostic techniques that fail to generate a definitive conclusion in more than 50% of cases.

The diagnosis of heart failure combines echocardiographic review with clinical examination of the patient. The ability to provide physicians with a clear risk assessment (based on echocardiographic measurements) prior to physical examination is expected to positively impact patient care leading to improved access to treatment and earlier risk warnings.

FDA Application

Upon completion of the clinical studies for its AI solution for heart failure, the Company intends to prepare and submit an application for FDA clearance. This application is expected to be made under the (expedited) 510(k) pathway.

Reimbursement

Heart Failure places a significant burden on the healthcare industry and the costs of caring for patients with heart failure are significant.

The condition affects millions of people and often leads to emergency patient hospital admissions which are expensive. Further, US hospitals also suffer financial penalties from health insurers when they fail to address increases in rates of patient readmission. As heart failure is already the world's leading cause of hospital readmission, solutions with the ability to positively influence this can be highly attractive.

Solutions that improve earlier detection and diagnosis of heart disease as well as enhancing risk prediction have the potential to improve the health economics of this condition.

For these reasons, Echo IQ's specialist US health insurance advisors have indicated that the Company's solution should qualify for US insurance reimbursement. Securing reimbursement codes for our solution would alleviate costs associated with EchoSolv when used by hospitals and Accountable Care Organisations ("ACO") and instead become a source of revenue for healthcare providers since it generates a (paid-for) fee each time it is used.

Most recently, new reimbursement codes have been issued for an image-based tool designed to improve detection of heart failure valued at US\$284 (on a standard "CPT" basis (Current Procedural Terminology) and US\$1,023 if qualifying as "NTAP" (New Technology Add-On Payment). Echo IQ estimates that of more than 30 million echocardiograms performed in the US each year, over 7 million of them are covered by Medicare for the evaluation of heart conditions and disease.

- (1) *Global burden of heart failure: a comprehensive and updated review of epidemiology* | Cardiovascular Research | Oxford Academic (oup.com).
- (2) *Heart failure* (baker.edu.au).
- (3) *Heart, stroke and vascular disease: Australian facts, Heart failure and cardiomyopathy* - Australian Institute of Health and Welfare (aihw.gov.au).
- (4) *Current and projected burden of heart failure in the Australian adult population: a substantive but still ill-defined major health issue* | BMC Health Services Research | Full Text (biomedcentral.com).
- (5) *Global burden of heart failure: a comprehensive and updated review of epidemiology* | Cardiovascular Research | Oxford Academic (oup.com).
- (6) *Burden of hospitalization for heart failure in the United States: a systematic literature review* | Journal of Managed Care & Specialty Pharmacy (jmcp.org).

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Authorised for release by the Board of Directors of Echo IQ Limited.

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ABOUT ECHO IQ

Echo IQ uses AI-driven technology and proprietary software to improve decision making in Cardiology. The company is based in Sydney, Australia.