

ASX: EIQ RELEASE 2 October 2025

# Strong operational momentum with multiple commercial and regulatory milestones achieved

- EchoSolv AS platform usage with fully integrated US customers has increased significantly with 153% increase in echocardiograms processed from July through September 2025
- Total echocardiograms analysed by EchoSolv AS platform globally has now exceeds 90,000, based on ongoing trials and business development initiatives
- Mayo Clinic Validation study scheduled to complete this month, prior to FDA submission for EchoSolv HF shortly thereafter – marks the final regulatory requirement prior to FDA Clearance
- ScImage onboarding and integration completed ahead of broader EchoSolv AS deployments in the US market through ScImage's 1,200 strong customer network
- Beta testing completed with SARC MedIQ ahead of broader outreach to 300 healthcare facilities in network
- Dr Phillipe Genereux appointed as strategic advisor Dr Genereux is an internationally recognised cardiologist and one of the world's leading authorities on structural heart disease
- US presence strengthened through appointment of Dr Asif Ali as an advisor Dr Ali is as leading cardiologist and key opinion leader in utilising AI to advance healthcare outcomes
- Multiple integrations pending within large US hospitals as part of advisor appointments
- Negotiations with European product distributor in final stages to unlock a new market entry, alongside pursuit of CE Mark to broaden global footprint of EchoSolv platform

**Sydney:** All and Medical Technology company Echo IQ ("the Company" or "Echo IQ") (ASX: EIQ) is pleased to provide the following progress update across workstreams in relation to the ongoing commercialisation of EchoSolv AS in the US market, regulatory clearance of EchoSolv HF, key personnel appointments and other initiatives.

### **Management commentary:**

Chief Executive Officer, Mr Dustin Haines said: "Echo IQ continues to build strong momentum across all key workstreams. Achieving a consistent growth rate of echocardiogram processing with fully integrated EchoSolv AS US customers has underpinned strong momentum to date in the American market and highlights increased usage of our technology ahead of a broader scale up and sales push across a range of qualified leads."

"At the same time, our FDA submission pathway for EchoSolv HF remains firmly on track, supported by the pending completion of our Mayo Clinic validation study in the coming weeks. This data will form an important foundation for our FDA submission, which will follow in quick succession upon completion of the trial and marks the final regulatory piece prior to FDA clearance in the coming months."



"With the addition of two new world-class advisors, new integrations with leading hospital networks, and strategic initiatives underway in both the US and European Union, Echo IQ is well positioned to accelerate the global adoption of our technology and deliver significant value to shareholders.

#### Increased uptake and utilisation of EchoSolv AS in US hospitals:

Echo IQ has undertaken extensive engagement with US hospital groups that are fully integrated with EchoSolv AS in recent months, which has underpinned a considerable increase in total echocardiograms processed through the platform.

From July through to September 2025, total echocardiograms processed using EchoSolv AS has increased 153% at key sites. This is a major milestone for the Company and provides considerable confidence for the continued use of the technology.

Upon completion of this engagement, the Company is now advancing a dedicated conversion strategy with a range of qualified leads. Final demonstrations and beta testing are underway with a number of large hospital groups and clinics in the US, with additional integrations expected to occur in the coming months.

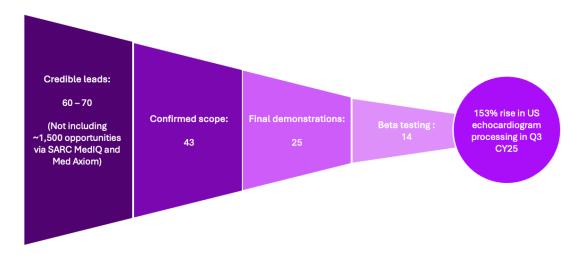


Image: Current sales and integration pipeline

The Company expects this increase in platform use to flow through to revenue during Q4 CY25, ahead of boarder scale up in CY2026 following an increased level of integrations across US hospital groups and clinics.

# Increased EchoSolv AS use through Australia and New Zealand pilot trial:

Further highlighting increased adoption, the Company advises that total retrospective echocardiograms analysed by EchoSolv AS through Australia and New Zealand in CY25 have now exceeded 50,000. The overall increase follows continued execution of the Company's fully funded medical device pilot trial with a leading global structural heart innovation company. The trial has been designed to utilise EchoSolv AS to assess quality assurance and patient recall programs across Australia and New Zealand to highlight at risk patients for further review, as well as a range of other domestic opportunities in the Australian



market with hospitals and clinics prior to potential regulatory engagement with the Therapeutic Goods Administration (TGA).

## Mayo Clinic Platform Validation study pending completion this month ahead of FDA submission:

The Company confirms its clinical validation study of EchoSolv HF in collaboration with the Mayo Clinic Platform, a division of the Mayo Clinic, a top ranked US hospital (refer ASX announcement: 1 July 2025), is expected to complete in the coming weeks.

The study is being undertaken in collaboration with Mayo Validate, a unique in-market AI evaluation program which generates an objective report on accuracy, efficacy and susceptibility to bias for AI-based decision software. The study is expected to validate the EchoSolv HF model's ability to detect heart failure on an independent dataset.

Data from the study will be pivotal in providing clinical evidence to support the Company's FDA 510(k) application for EchoSolv HF in the US market, which is scheduled to be submitted in the coming weeks.

FDA Clearance for EchoSolv HF will unlock a significant market opportunity for the Company. Heart failure is the leading cause for rehospitalisation in the US and accounts for 17% of all healthcare expenditure in the country. It has a total market size of US\$60Bn, which is expected to grow due to the under-utilisation of evidence-based therapies like EchoSolv HF and rising mortality rates. It is now estimated that one in four Americans will develop heart failure in their lifetime<sup>i</sup>.

### Completion of onboarding and integration with Scimage:

Echo IQ and ScImage have advanced negotiations with multiple sites and anticipate accelerated integrations through the partnership to occur in the coming weeks. Concurrently, additional testing is being undertaken through the ScImage and MedAxiom network which is expected to further increase integrations. ScImage and MedAxiom network (refer ASX announcement 31 March 2025) is a nationally recognised cloud and integrated workflow management platform, which has over 1,200 users in the US.

#### Completion of Beta testing with SARC MedIQ:

Echo IQ advises it has completed final beta testing initiatives with SARC MedIQ, following execution of a reseller agreement with the group (refer ASX announcement: 10 July 2025).

Echosolv AS has now been fully Beta tested and ready for final integration into SARC MedIQ's unique partnership-based PACS (Picture Archiving and Communication) Solution, which services over 300 healthcare facilities and 1,500 physicians in the US. Further, SARC MedIQ's sales force are now actively pursuing leads across the group's network to advance integration opportunities.

#### Appointment of Dr Phillippe Genereux as strategic advisor:

Echo IQ has further strengthened its US presence through the appointment of Dr Phillipe Genereux as a strategic advisor. Dr Genereux is an internationally recognised interventional cardiologist and one of the world's leading authorities on structural heart disease. He serves as Medical Director of the Structural Heart Program at Morristown Medical Center (New Jersey).



Over his 15-year career, he has acted as primary or co-investigator on over 20 clinical trials and has authored or co-authored more than 300 peer-reviewed publications. Dr Genereux's research leadership has been widely recognised, having served as the principal investigator to major trials including EARLY TVAR and PROGRESS, which focused on aortic valve disease. He has also been named amongst the world's most highly cited researchers for multiple consecutive years.

As part of his role, Dr Genereux will assist in driving EchoSolv uptake through his extensive US network and assist in pending regulatory submissions. Echo IQ is also working with Dr Genereux to advance integration of EchoSolv AS at the Morristown Medical Center, which boasts 735 beds and serves the Northern New Jersey and New York metropolitan area.

#### Dr Asif Ali appointed as strategic advisor:

To bolster the Company's US presence, Echo IQ has also appointed Dr Asif Ali as a strategic advisor. Dr Ali is a Clinical Associate Professor of Cardiovascular Medicine at the University of Texas Medical School, Houston and a partner at Houston Cardiology Consultants. He holds a BS in Biology from Trinity University (San Antonio) and earned his MD from the University of Texas Health Science Center in Houston. Dr Ali completed his residency in Internal Medicine followed by fellowship training in cardiovascular medicine and advanced cardiovascular imaging before joining private practice.

Dr Ali leads care in cardiovascular and autonomic conditions at Houston Cardiology Consultants, combining traditional cardiology with digital diagnostics and a focus on health equity. He is also active in the health-tech and innovation space, serving on the American Heart Association's Health Tech Advisory Group and contributing to committees on Al and cardiovascular metabolic-renal integration.

Dr Ali is published in peer-reviewed journals and contributes to clinical education, serving various leadership roles including Chief Medical Officer, Chief of Education, and Chief of Cardiology across various institutions in Houston. In addition, Dr Ali serves as a member of the American Heart Association's Health Tech Advisory Group, advancing the use of digital health technologies and remote patient monitoring to improve cardiovascular outcomes.

Echo IQ will leverage Dr Ali's extensive expertise to further refine EchoSolv's commercial offering for the US market, as well as unlock integration opportunities. Negotiations with both Houston Cardiology Consultants and the University of Texas Medical School are well advanced following his appointment.

#### European Union expansion via pending distribution agreements and regulatory engagement:

EcholQ is also in advanced negotiations with a specialist distributor within the European Union to progress sales and regulatory clearance of EchoSolv technology across the region.

Alongside its US commercialisation strategy, the EU represents another large market opportunity for the Company. Aortic Stenosis is one of the most common heart valve conditions in Europe, with a recorded mortality rate of over 50% at one year if left unmanaged<sup>ii</sup>, while Heart Failure underpins €29 billion annually in direct costs alone to the EU, affecting an estimated 2% of the population and rising due to Europe's aging populace<sup>iii</sup>.

Echo IQ intends to finalise a binding agreement with the counterparty in the coming weeks, while also actively pursuing regulatory engagement to gain CE Mark approval across the EU.



# Global health economic outcome study underway alongside National Echo Database Australia (NEDA):

To increase supportive evidence for EchoSolv and further highlight the solution's potential, the Company has commenced a health economic outcome study alongside NEDA. The study will evaluate the clinical and economic impact of earlier, AI-driven identification of prognostically significant aortic stenosis and heart failure with key outcomes to include mortality and hospitalisation rates, surgical intervention trends, health system costs and resource utilisation. If successful, findings could demonstrate significant cost savings and reduced mortality through earlier intervention – reinforcing the value of Echo IQ's AI technology in proactive cardiac care.

Echo IQ is pleased to reaffirm its ongoing Technology Access Agreement with NEDA Limited, maintaining exclusive commercialisation rights for the Echo IQ project. NEDA remains an independent research organisation, and this agreement fully supports its continued non-commercial research and charitable initiatives under its ethical framework. NEDA may also pursue non-competitive commercial activities outside the scope of the Echo IQ project. This enduring collaboration reflects a shared commitment to advancing cardiac care and improving outcomes for millions affected by heart disease worldwide

The initiative is expected to bolster work underway with Beth Israel Deaconess Medical Center, a leading Harvard Medical Teaching Hospital, which is focused on patient outcomes for individuals with moderate of severe aortic stenosis at one year, compared to patients that receive treatment at Beth Israel (refer ASX announcement: 5 March 2025).

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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 Al-driven technology and proprietary software to improve decision making in Cardiology.

The company is based in Sydney, Australia.



<sup>&</sup>lt;sup>1</sup> https://hfstats.org/stat-category/incidence-prevalence-and-lifetime-risk-estimates-of-hf-in-the-us/

https://www.frontiersin.org/journals/cardiovascular-medicine/articles/10.3389/fcvm.2021.748137/

https://ehnheart.org/wp-content/uploads/2023/08/EHN-heart-failure-paper\_final\_180419.pdf?