



## Agreement with Mayo Clinic in preparation for potential FDA clearance of EchoSolv HF

- Agreement enables Mayo Clinic to resell and distribute EchoSolv HF following FDA clearance
- EchoSolv HF will be deployed via Mayo Clinic Platform – Solutions Studio Program, providing Mayo hospitals, health system network and 80+ external partner hospitals the ability to participate
- Revised agreement includes improved commercial terms and automatic extension for a potential 6-year agreement
- Platform-enabled distribution provides a scalable pathway to revenue and broader adoption across US hospital network
- Agreement positions Echo IQ for potential commercial deployment and revenue generation following FDA clearance
- FDA clearance has the potential to unlock a significant market with only ~50% of heart failure cases accurately diagnosed and ~1 in 4 Americans expected to develop the condition in their lifetime

**Sydney:** AI and Medical Technology Company Echo IQ Limited (ASX: EIQ) (“Echo IQ” or “the Company”) is pleased to advise it has expanded its agreement with the Mayo Foundation for Medical Education and Research (“Mayo”), a legal, non-profit entity of the Mayo Clinic, a top-ranked US hospital to resell and distribute the Company’s heart failure clinical decision support solution (“EchoSolv HF”) following clearance from the US Food & Drug Administration (“FDA”).

Under the agreement terms, EchoSolv HF will be offered through the Mayo Clinic Platform (“MCP”) – Solutions Studio Program to Mayo Clinic Hospitals, Mayo Clinic Health System Network and non-Mayo Clinic hospitals utilising the MCP Solutions Studio Program following receipt of FDA clearance.

The revised agreement strengthens the commercial framework between the parties and supports the planned deployment of EchoSolv HF within the Mayo Clinic Platform. Under the original terms (refer ASX announcement: 3 April 2025), Mayo retained the right to resell and distribute EchoSolv HF upon receipt of FDA clearance within the Mayo network. The amended agreement reflects a more equitable financial arrangement between the parties and now includes an automatic renewal term of three years following the initial three-year term, extending the potential commercial partnership to six years.

The expanded agreement follows a validation study conducted through the Mayo Clinic Platform validation program (refer ASX announcement: 24 November 2025). The study met its primary endpoint, with EchoSolv HF demonstrating a sensitivity of 99.5% in identifying patients with heart failure and a specificity of 91.1% in correctly identifying patients without heart failure. These results have not been reviewed or cleared by the FDA and are subject to the FDA’s regulatory review process.

Following this study, the Company lodged its market clearance application for EchoSolv HF with the FDA via the 510(k) premarket notification pathway (refer ASX announcement: 15 December 2025). The Company advises that it is currently progressing through the FDA review process and will provide additional updates as developments materialise.

Clearance has the potential to unlock a significant market opportunity for Echo IQ. Heart failure represents a substantial and growing burden on the US healthcare system, with ~6.7m Americans currently living with the condition and an estimated 2m more patients remaining undiagnosed. Upwards of 16m echocardiograms are



performed in the US per annum, with around 8m studies containing heart failure-relevant findings, representing approximately 50% of all echocardiographic exams.

Following receipt of FDA clearance, Echo IQ is now positioned to deploy EchoSolv HF via the Mayo Clinic Platform, providing potential access to a high-volume clinical network and established distribution pathway. This development represents a key step in the Company's strategy of converting clinical validation into potentially revenue-generating installations, while also supporting broader adoption across additional hospital networks and platform participants.

## **Management commentary:**

**Chief Executive Officer, Mr Dustin Haines, said:** *"The expansion of our agreement with Mayo Clinic is one of the more strategically important milestones in the Company's history. A more equitable arrangement with one of the most respected hospital systems in the US, as we move closer to FDA clearance and commercial deployment, leaves us well positioned for the months ahead."*

*This milestone reflects the strength of the EchoSolv HF clinical utility and the growing commercial value of the solution, while the revised agreement provides a scalable pathway to market through the Mayo Clinic Platform. This may give us access to Mayo's hospital network and a broader ecosystem of healthcare providers seeking validated AI solutions.*

*While our application with the FDA is still under review, we continue to remain confident in our submission. While this review process is ongoing our focus is on preparing for rapid commercial rollout, expanding our network of US healthcare partners, and positioning the Company's EchoSolv technology as a standard decision support tool within cardiac imaging workflows."*

Important Regulatory Notice: EchoSolv HF has not received clearance from the United States Food and Drug Administration (FDA) and is not currently available for commercial sale or distribution in the United States. The Company's 510(k) premarket notification application is currently under FDA review, and there can be no assurance as to the timing or outcome of that review process. All commercial arrangements, distribution rights, and deployment activities described in this announcement are contingent upon, and would only become operative following, receipt of FDA clearance.

## **SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995:**

To the extent any statements in this announcement contains information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (collectively, the "PSLRA"). This announcement contains forward-looking statements regarding Echo IQ's expectations, intentions, and projections regarding future events, including statements about the timing and outcome of the FDA 510(k) review, potential FDA clearance of EchoSolv HF, commercialisation plans, market opportunities, and expected product performance. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "expect," "estimate," "plan," "will," "would," and similar expressions. These forward-looking statements are based on current expectations and assumptions and are subject to risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied by such statements.

Key risks and uncertainties include, but are not limited to: market adoption by healthcare professionals and institutions; reimbursement coverage uncertainty, including payer-by-payer CPT coding decisions and evolving healthcare spending trends; competitive factors and the development of alternative technologies;



post-market surveillance requirements and ongoing FDA compliance obligations applicable to AI/ML Software as a Medical Device; the ability to convert existing relationships and distribution channels into revenue-generating deployments; regulatory requirements that may change or differ from expectations; and the Company's ability to execute its commercialisation strategy at scale. The Company's ability to achieve the market opportunities described in this announcement is subject to numerous factors beyond its control.

Actual results, performance, or achievements may differ materially from those expressed or implied in forward-looking statements. The forward-looking statements in this announcement are made as of the date hereof, and Echo IQ assumes no obligation to update or revise any forward-looking statements, whether because of new information, future events, or otherwise, except as required by applicable law, including the securities laws of the United States and ASX Listing Rules. Investors are cautioned not to place undue reliance on forward-looking statements. The Company cautions readers that the foregoing list of important factors is not exhaustive and encourages readers to review the detailed risk factors included in the Company's filings with the ASX for a more complete discussion of factors that could affect the Company's future results.

Forward-looking statements in this announcement are made on reasonable grounds as required by section 769C of the Corporations Act 2001 (Cth), however actual results may differ materially from those expressed or implied. The Company is under no obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law including the ASX Listing Rules.

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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.

**ABOUT MAYO CLINIC**

Mayo Clinic is a nonprofit academic medical centre based in the United States, focused on integrated clinical practice, education and research. It is consistently ranked among the top hospitals globally and is recognised for excellence across a wide range of medical specialties, including cardiology and cardiovascular surgery.

Mayo Clinic operates major campuses in Rochester, Minnesota; Phoenix/Scottsdale, Arizona; and Jacksonville, Florida, alongside a broader health system and the Mayo Clinic Care Network, which extends its expertise to healthcare providers across the United States and internationally. Through the Mayo Clinic Platform, the organisation also supports the development and deployment of innovative healthcare technologies aimed at improving patient outcomes and advancing the practice of medicine.