ECHO IQ LIMITED | ASX:EIQ

Quarterly Report

to 31 December 2024

EchoIQ

www.EchoIQ.ai

ASX Release

31 December 2024 Quarterly Report

Echo IQ uses AI-driven technology and proprietary software to improve decision making in cardiology.

CORPORATE

Issued Capital (As at 31 December 2024)

- 588,521,043 Ordinary Shares
- 88,475,000 Unlisted Options
- 4,700,000 Performance Rights

Shareholders

- 3,194 Shareholders
- Top 20 Shareholders hold 43.30%

Cash Balance

- As at 31 December 2024, Echo IQ held $5.35M in cash (and cash equivalents).

DIRECTORS

Andrew Grover, Executive Chair
Steve Formica, Non-Executive Director
Steve Picton, Non-Executive Director
Ken Nelson, Non-Executive Director
Jessamyn Lyons, Company Secretary

CONTACT

investors@echoiq.ai

Highlights

The period from 1 October 2024 to 31 December 2024 included a number of significant activities demonstrating strong progress towards the Company's strategic objectives.

- Key regulatory approval for EchoSolv AS with confirmation of 510(k) clearance from the US Food & Drug Administration (FDA)
- FDA clearance allows for EchoSolv AS to be marketed to and used by healthcare professionals in the USA – a critical milestone for commercial adoption of the technology
- Formal appointment of US-based CEO, Mr Dustin Haines, to spearhead commercialisation strategy followed successful FDA clearance
- Flagship deployment of EchoSolv AS with Beth Israel Deaconess Medical Center, a world-class teaching hospital of Harvard Medical School
- Beth Israel undertakes approximately 30,000 echocardiograms per annum and will serve as a platform for further uptake in the US market
- Appointment of Mr Ken Nelson, a leading US-based medical technology and healthcare executive, as Non-Executive Director
- Mr Nelson's appointment further strengthens EIQ's US presence ahead of further commercialisation initiatives
- Miscellaneous code for EchoSolv AS reimbursement identified – expected to provide a reimbursement rate of between US$100 to US$150 to users on a fee-per-use basis
- Additional steps towards filing for Category III CPT code to streamline reimbursement of technology in the US – Category III CPT anticipated mid-CY25
- Lodgement of pre-submission meeting request with the FDA to approve trial design parameters for EIQ's unique heart failure screening tool, EchoSolv HF
- Meeting to be undertaken in the coming months with proposed validation trial to commence shortly thereafter – Negotiations with potential clinical trial partners are very well advanced
- Pipeline of opportunities for EchoSolv AS with large hospital groups, pharmaceutical companies and device manufacturers in the US continues to strengthen

AI and Medical Technology company Echo IQ (“the Company” or “Echo IQ”) (ASX:EIQ) is pleased to provide the following update on activities undertaken during the three month period ended 31 December 2024 (the ‘quarter’). During the period, the Company achieved a number of major milestones which have laid a strong foundation for its ongoing commercialisation strategy.

MANAGEMENT COMMENTARY:

“The December quarter was a defining period for Echo IQ, marked by the Company’s transition from clinical development to commercial adoption for our flagship EchoSolv AS technology, following FDA clearance in October 2024.

“The Company now has a major opportunity to expand the commercial adoption of our technology in the US healthcare sector, and our recent initiatives following FDA clearance - undertaken at both an operational and strategic level - have been implemented with this objective in mind. As CEO, I am thrilled to apply my direct experience in commercialising med-tech products in the US healthcare sector to support the mass-scale adoption of EchoSolv AS, which is already a unique success story for Australia’s medical technology sector. Through a comprehensive clinical development pathway, the Company and its research partners have demonstrated that the EchoSolv AS technology has the capacity to generate improved health outcomes via more accurate early detection rates for severe Aortic Stenosis – one of the primary forms of structural heart disease globally.

“I look forward to working with our commercial partners alongside US health regulators to support the adoption of EchoSolv AS in 2025, alongside the ongoing clinical approval process for EchoSolv HF.”

Chief Executive Officer, Mr Dustin Haines

FDA CLEARANCE SECURED FOR ECHOSOLV AS:

In a major development, Echo IQ received 510(k) clearance from the US Food and Drug Administration (FDA) for EchoSolv AS. This allows for the solution to be marketed to and used by healthcare professionals in the US as a decision support aid in the detection of severe Aortic Stenosis (AS).

Clearance followed formal submission in May 2024 and following a detailed review process, the FDA determined Echo IQ had demonstrated substantial equivalence to the predicate device referenced in the Company's submission.

Securing FDA clearance has allowed the Company to advance ongoing discussions with a number of large hospital groups, device manufacturers and pharmaceutical companies, as part of Echo IQ's commercialisation strategy.

US BASED CEO APPOINTED TO EXECUTE COMMERCIALISATION:

Mr Dustin Haines was appointed as CEO during the quarter, commencing subsequent to the end of the period. Mr Haines has 25 years' experience as a leading healthcare executive.

Most recently, he was Vice President & General Manager of Gilead Sciences, Asia, Middle East, Turkey and Russia. During this time, he led business development across several product categories including infectious disease, oncology and immunology. Gilead Sciences is a NASDAQ listed biopharmaceuticals company with a market capitalisation of US$105Bn.

Prior to this, he was Chief Commercial Officer at medical technology company, Next Science Limited (ASX: NXS). Mr Haines also spent over a decade in senior roles with ViiV Healthcare and GSK (GlasxoSmithKline), where he was instrumental in delivering Phase 3 assets through to category leading commercialisation.

As CEO, Mr Haines is focused on executing Echo IQ's US commercialisation strategy. As part of his appointment, Mr Andrew Grover transitioned from interim Managing Director to maintain his role as Executive Chair post quarter end.

INTEGRATION AGREEMENT WITH BETH ISRAEL DEACONESS MEDICAL CENTER, BOSTON USA:

Echo IQ commenced integration of EchoSolv-AS with Beth Israel Deaconess Medical Center ('Beth Israel' or 'BIDMC'), a leading Harvard Medical Teaching Hospital. This marked Echo IQ's flagship deployment of EchoSolv AS with a major hospital group in the US.

BIDMC is a specialist academic medical centre, specialising in the latest technologies and teaching initiatives. It has 743 licensed beds, oversees 37,606 inpatient discharges annually and has circa 50,000 emergency department visits and 803,000 outpatient visits per annum. The organisation undertakes approximately 30,000 echocardiograms annually.

The integration is expected to further validate EchoSolv AS in real life practice and follows the completion of a successful trial with the group in September 2024 which validated EchoSolv AS' key performance metrics.

The flagship integration will provide unparalleled exposure for EchoSolv AS in the US and is expected to generate additional real-world data to highlight the technology's benefit.
The Company is confident that this integration will also assist in converting its pipeline of potential customers.

MISCELLANEOUS CODE IDENTIFIED FOR ECHOSOLV AS REIMBURSEMENT:

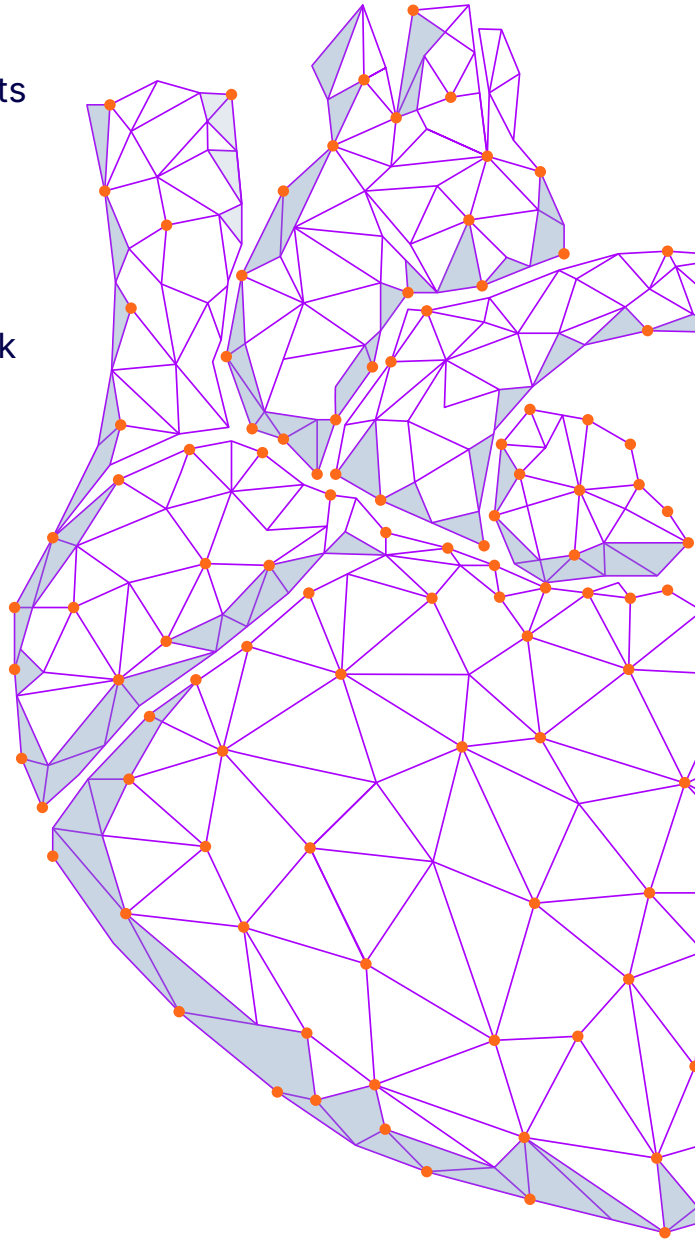
The Company furthered reimbursement strategy by identifying Miscellaneous Code 93799 for EchoSolv AS. This code is expected to provide a reimbursement rate of between US$100 to US$150 to users of the technology on a fee-per-use basis and is considerably higher than the previous estimate of US$68.

Reimbursement from insurance providers is a primary catalyst for commercial adoption of medical devices by end-users in the US healthcare sector.

Identification followed considerable engagement with reimbursement and market access consultants and provides Echo IQ with the opportunity to split the total reimbursement amount with hospital groups, with the Company to receive between 30-60% of the total rate.

EchoSolv AS integration sites are now able to work directly with payers to utilise the code and seek reimbursement for use of the technology. To support this process, the Company also created a cache of supporting documentation which can assist in gaining reimbursement.

Concurrently, Echo IQ has taken steps to file for a Category III CPT code, which will create a code for utilisation of EchoSolv AS as a new or emerging technology and marks an important step in progress towards a designated CPT code. The Company will file for a Category III CPT code in February 2025 and anticipates approval by mid-CY25. This is expected to further streamline reimbursement for users.



APPOINTMENT OF CARDIAC FOCUSED US-BASED NON-EXECUTIVE DIRECTOR:

Considerably strengthening the Company's US presence, Mr Ken Nelson was appointed as a Non-Executive Director, effective 11 December 2024. As part of the appointment, Mr Simon Tolhurst tendered his resignation to the Board.

Mr Ken Nelson is a leading US-based medical technology and healthcare executive with over 20 years' industry experience. During his career he has been pivotal in leading successful commercialisation efforts with multiple cardiac-focused digita BioTelemetry, wearable device company, iRhythm and ambulatory ECG solutions monitoring group, Bardy Diagnostics. Currently, he serves as partner in the Medtech Advantage Fund, which has an exclusive partnership with Medtech Innovator (www.medtechinnovator.org), the largest medical technology and digital health startup accelerator globally.

Mr Nelson has an extensive network in the global medical technology sector and strong relationships with a large cohort of sophisticated healthcare investors. This network is expected to be beneficial as Echo IQ continues to execute its commercialisation strategy.

PRE-SUBMISSION MEETING REQUESTED WITH THE FDA FOR HEART FAILURE DECISION SUPPORT SOLUTION:

Echo IQ furthered its regulatory strategy, formally submitting a request to the FDA for a pre-submission meeting to approve the design for its proposed validation trial. The trial, expected to be undertaken in the US in the coming months, will test its heart failure screening tool (EchoSolv HF) in detecting various forms of heart failure.

Heart failure is a widespread condition. It is the leading cause of re-hospitalisation in the US and accounts for 17% of all US healthcare expenditure[i]. The market for heart failure is estimated at US$60Bn[ii] annually and presents a major opportunity for Echo IQ.

The pre-submission meeting is expected to occur this quarter. During the meeting, Echo IQ will liaise with the regulator on its dossier on EchoSolv HF and confirm the clinical trial design of its validation study. This study is anticipated to be the final clinical requirement, prior to formal submission for clearance. Clearance for EchoSolv HF is expected during H2 CY25.

OUTLOOK:

The Company remains focused on advancing a number of value accretive objectives during the current quarter, including:

- Convert its US pipeline of large US hospital groups, device manufacturers and pharmaceutical companies to increase integration and uptake of EchoSolv AS
- Advance steps towards a Category III CPT code and designated CPT code for Echosolv AS allowing for seamless reimbursement for users in the US
- Finalise agreements with a US-based trial partner for proposed EchoSolv HF validation study and complete site selection
- Commence validation study following design approval from the FDA ahead of formal submission for clearance

CORPORATE:

The Company's cashflow report for the three-month period ended 31 December 2024 follows this announcement. Cash and cash equivalents at 31 December 2024 were $5.35m. Further to this, the Company also expects to receive $1.2m as part of an R&D tax rebate in the current quarter which will add additional balance sheet strength. Staff costs, administration and corporate costs rose slightly on last quarter, due to one off costs associated with restructuring the Company's Australian operations.

During the quarter, $281,000 in payments were made to relayed parties and their associates for director salaries, fees, superannuation and other related costs.

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

[i] https://academic.oup.com/cardiovascres/article/118/17/3272/6527627?login=false

[ii] https://pubmed.ncbi.nlm.nih.gov/35085762/

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Echo IQ Limited	
ABN	**Quarter ended ("current quarter")**
48 142 901 353	31 December 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	200	200
1.2	Payments for		
	(a) research and development	-	-
	(b) product manufacturing and operating costs	(362)	(753)
	(c) advertising and marketing	(5)	(26)
	(d) leased assets	-	-
	(e) staff costs	(1,132)	(2,023)
	(f) administration and corporate costs	(518)	(862)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	56	56
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,761)**	**(3,408)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(3)	(3)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(3)**	**(3)**
3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	7,105
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(11)	(461)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(11)**	**6,644**
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,118	2,117
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,761)	(3,408)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(3)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(11)	6,644
4.5	Effect of movement in exchange rates on cash held	10	3
4.6	**Cash and cash equivalents at end of period**	**5,353**	**5,353**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	5,353	7,118
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**5,353**	**7,118**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(281)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-
7.5	**Unused financing facilities available at quarter end**		-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,761)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,353
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,353
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.	
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
	8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	N/A	
	8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	N/A	
	8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	N/A	
	Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.	

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 30 January 2025

Authorised by: The Board

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.