

ECHO IQ LIMITED / ASX:EIQ

QUARTERLY REPORT

TO 30 SEPTEMBER 2024

Echo **IQ**

WWW.ECHOIQ.AI

ASX RELEASE

**30 SEPTEMBER 2024
QUARTERLY REPORT**

Echo IQ uses artificial intelligence proven to enhance detection of structural heart disease.

CORPORATE

ISSUED CAPITAL

(As at 30 September 2024)

588,521,043 Ordinary Shares
106,475,000 Unlisted Options
3,000,000 Performance Rights

SHAREHOLDERS

2,292 Shareholders
Top 20 Shareholders hold 46.6%

CASH BALANCE

As at 30 September 2024, Echo IQ held \$7.118 million in cash (and cash equivalents).

CONTACT

investors@echoiq.ai

DIRECTORS

Andrew Grover / Executive Chair
Steve Formica / Non-Executive Director
Steve Picton / Non-Executive Director
Simon Tolhurst / Non-Executive Director

Jessamyn Lyons / Company Secretary

HIGHLIGHTS

The period 1 July 2024 to 30 September 2024 included a number of significant activities demonstrating strong progress towards the Company's strategic objectives.

- 1 Strategic integration partnership with ScImage Inc. (4 July 2024)
- 2 Positive results in two clinical studies for Echo IQ AI algorithm for heart failure (3 September 2024)
- 3 Heart Failure AI featured in two late-breaking science presentations at ESC Congress (3 September 2024)
- 4 \$7.1m capital raised (before costs) in oversubscribed placement (6 September 2024)

POST-QUARTER

- 5 FDA Clearance secured for EchoSolv-AS (8 October 2024)
- 6 Appointment of new US-based Chief Executive Officer effective 10 January 2025 (9 October 2024)

Strategic Integration Partnership with ScImage Inc.

ScImage®



Echo IQ announced (4 July 2024) that it had entered into a strategic integration partnership with ScImage Inc. ("ScImage") of Los Altos, California. ScImage provides cloud-native enterprise image management, PACS and image exchange solutions for the healthcare industry. Under the terms of the agreement, ScImage will incorporate Echo IQ's EchoSolv-AS decision-support software into its PICOM365 Cloud image management and reporting platform.

ScImage will incorporate Echo IQ's EchoSolv decision support for Aortic Stenosis, in the first instance, into ScImage's PICOM365 Cloud image management and reporting platform. This is expected to give users of the platform access to high-quality, automated AI-backed echocardiography assessments designed to facilitate faster, more accurate diagnoses of this life-threatening but treatable condition. ScImage has 2000 sites using its PICOM365 platform in the US and is one of the largest providers in its field. Initially, this integration partnership is expected to see EchoSolv's automated assessment capabilities rolled out to several key US cardiology practices and strategic hospitals before the end of 2024.

Positive Clinical Study Results

Echo IQ was pleased to announce (3 September 2024) ground breaking results from its two recently completed clinical studies performed in collaboration with leading Australian research centres: The Screen-HF Study with St. Vincent's Institute of Medical Research and the NIL-CHF Study with The University of Notre Dame, Fremantle, for its novel AI-algorithm as a heart failure decision support tool.



These results highlighted the effectiveness of its AI-backed solution for heart failure when compared to an observed detection rate of 46%⁽¹⁾ in clinical practice and demonstrated that:

- Echo IQ's AI technology without human review clearly and correctly identified 86% of patients with heart failure, in comparison to a matched group without heart failure (data from the application of the Echo IQ AI technology to participants from the SCREEN-HF study).

Positive Clinical Study Results (contd.)

- Echo IQ's AI to aid human review of patients identified 97% of high-risk individuals that subsequently developed heart failure (data from the application of the Echo IQ AI technology to participants from the NIL-CHF study)

Heart failure symptoms can include breathlessness, leg swelling and fatigue. Since the symptoms are not specific to heart failure, it is difficult to diagnose heart failure from symptoms alone. Current guidelines mandate additional evidence from echocardiography to confirm the diagnosis. Once the diagnosis is correctly made, treatment for heart failure is clearly defined according to clinical practice guidelines, and has a significant impact on survival. Hence, making an accurate diagnosis is of utmost importance.

The Company expects its AI-backed solution may enhance a doctor's potential to identify people with, or at risk of, heart failure, potentially optimising treatment choices for these individuals.

Exposure at ESC Congress 2024, London



On 3 September, 2024 the Company announced that it had featured in two late-breaking science presentations at the European Society of Cardiology ("ESC") Congress in London, UK. The results of the clinical studies for Echo IQ's AI algorithm for heart failure were presented, following peer review and invitation, at the world's preeminent forum for advancing cardiovascular research and treatment.

Echo IQ has now been featured in four late-breaking science presentations in the last two ESC Congress events. This is an exceptional honour and is testament to the quality and innovation of Echo IQ's work in this space. This kind of exposure provides Echo IQ with an exceptional springboard to broaden its footprint in a major global market, which has a number of diagnostic related challenges. The results which were presented and the feedback the Company received from the event have highlighted that our innovation is a medical necessity for improving patient outcomes.

Regulatory Pathways

Following the presentation of these results at ESC Congress 2024, the Company remains well placed to advance its regulatory strategy with an application for US FDA clearance for its heart failure solution. Work is now underway toward a pre-submission meeting with the regulator, which will provide additional insight into its clearance pathway.

Concurrently, Echo IQ has been engaging with a number of leading global pharmaceutical companies and device manufacturers, with both on-market and planned therapies for heart failure and associated conditions. These results are expected to advance these discussions ahead of potential commercial uplift with counterparties.

Reimbursement

Echo IQ is currently focused on securing CMS codes (Centers for Medicare & Medicaid Services) for reimbursement under health insurance for its software, working alongside its specialist US consultancy. This is expected to be boosted by the recent FDA clearance secured as well as upcoming deployments of EchoSolv-AS in clinical practice. Reimbursement codes create financial incentives for more widespread use of EchoSolv AS in US hospital settings on a fee-per-use basis.



Capital Raise \$7.1m

As announced on 6 September, 2024, Echo IQ raised \$7.1 million (before costs) in a placement of new fully paid ordinary shares in the Company to institutional and sophisticated investors. Proceeds from the placement will primarily be used to fund commercialisation activities for the Company's Aortic Stenosis and Heart Failure AI solutions as well as ongoing AI product development. The placement saw new institutional shareholders join the Echo IQ register as well as participation from several existing shareholders. Ord Minnett acted as Lead Manager in this placement.

POST-QUARTER

FDA Clearance for EchoSolv-AS

On 8 October 2024 the Company was pleased to advise that it had received 510(k) clearance from the US Food and Drug Administration ("FDA") for EchoSolv AS, allowing for the solution to be marketed to and used by healthcare professionals in the USA as a decision support aid in the detection of severe Aortic Stenosis.

The clearance followed a formal submission in May 2024 (refer ASX announcement: 7 May 2024). Following detailed review, the FDA determined that the Company demonstrated substantial equivalence to the predicate device cited in this submission, and has cleared it for marketing and use in the US.

Prior to securing FDA clearance, Echo IQ had been advancing discussions with a number of parties including large hospital groups, device manufacturers and pharmaceutical companies, on the commercial and clinical benefits of EchoSolv AS. As such, the Company is now exceptionally well placed to convert these negotiations into material agreements. The Company now has the ability to commercialise its technology in the world's largest and most well-regulated market, for a condition which is widespread and chronically underdiagnosed.

New CEO Appointment

On 9 October 2024, the Company announced that senior healthcare executive, Mr Dustin Haines, had been appointed as Chief Executive Officer, effective 10 January 2025. Dustin will be based in the US to spearhead the Company's strategy. He has exceptional experience, stemming from a 25-year career in the biotechnology and pharmaceutical sectors.

As CEO, Mr Haines will be focused on executing the Company's stated growth strategy starting with commercialisation in the US market, which will include obtaining relevant market access and reimbursement of the Company's technology. Mr Haines has extensive experience with building high performing teams and bringing innovation to the market. Mr Haines, a US citizen and seasoned American healthcare executive, was most recently Vice President & General Manager of Gilead Sciences, Asia, Middle East, Turkey and Russia.



New CEO Appointment (contd.)

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, which is focused on delivering innovative therapies in areas of great unmet needs.

Andrew Grover, Executive Chair, said: *“Dustin is joining the Company at a pivotal time in Echo IQ’s growth and development and was selected because of his extensive experience in delivering commercial outcomes across the healthcare industry. As a US-based executive, we will have the ability to leverage his extensive network in the world’s largest healthcare market to drive sales growth for EchoSolv.”*

References:

(1) Sandhu AT, Tisdale RL, Rodriguez F, Stafford RS, Maron DJ, Hernandez-Boussard T, Lewis E, Heidenreich PA. Disparity in the Setting of Incident Heart Failure Diagnosis. *Circ Heart Fail.* 2021 Aug;14(8):e008538. doi: 10.1161/CIRCHEARTFAILURE.121.008538. Epub 2021 Jul 27. PMID: 34311559; PMCID: PMC9070116.

CORPORATE

30 SEPTEMBER 2024 QUARTERLY REPORT

In accordance with the ASX Listing Rules, the Company has also lodged its cashflow report for the three-month period ended 30 September 2024.

The Company held total cash and cash equivalents of \$7.118M as at 30 September 2024.

Cash used in operations remained steady with recent quarters.

The Company raised \$6.655M in new capital, after capital raising costs of \$450,000.

As also outlined in the attached Appendix 4C (section 6), during the quarter \$138,000 in payments were made to related parties and their associates for director salaries, fees, superannuation and other related costs.

DECEMBER 2024 QUARTER OUTLOOK

Echo IQ's focus for the current quarter is to:

- Advance plans for application of reimbursement codes in US insurance market.
- Capitalise on recent FDA clearance to accelerate adoption of EchoSolv-AS
- Advance pathways to clearance for new heart failure AI solution
- AGM to be held 10:00 on 12 November, 2024 (Sydney)
- Company expects to lodge claim for more than \$1m Research + Development Tax Incentive.

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

Appendix 4C

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

Name of entity

Echo IQ Limited

ABN

48 142 901 353

Quarter ended ("current quarter")

30 September 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	-	-
(b) product manufacturing and operating costs	(391)	(391)
(c) advertising and marketing	(21)	(21)
(d) leased assets	-	-
(e) staff costs	(891)	(891)
(f) administration and corporate costs	(344)	(344)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
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	(1,647)	(1,647)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
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.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,105	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	(450)	(450)
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	6,655	6,655

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,117	2,117
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,647)	(1,647)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,655	6,655
4.5	Effect of movement in exchange rates on cash held	(7)	(7)
4.6	Cash and cash equivalents at end of period	7,118	7,118

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	7,118	2,117
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)	7,118	2,117

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	(138)
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.

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

7.	Financing facilities <i>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.</i>	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)	(1,647)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,118
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,118
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.3
	<i>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.</i>	
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	
	<i>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.</i>	

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: **25 October 2024**

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.