Echo IQ Limited

EIQ.AX – INITIATION OF COVERAGE

MST Access

A research platform of MST Financial

7 June 2023

Leveraging Exclusive Big Data to Enhance Heart Disease Diagnosis

NEED TO KNOW

- Empowering cardiologists with assistive AI
- Targeting major heart disease; focus on aortic stenosis
- Commercialisation underway with strategic alliances; FDA study/clearance to unlock reimbursement

AI-driven algorithms leveraging big cardiac data, medical expertise: Echo IQ (EIQ) has developed a cloud-based decision-support software platform, EchoSolv™, powered by AI and machine learning in consultation with cardiologists and supported by a well credentialled scientific advisory board. Its first application is supporting cardiologists in using echocardiograms (echoes) to diagnose aortic stenosis (AS), the most common form of heart valve disease and one associated with poor prognosis and high mortality.

Exclusive access to the National Echo Database of Australia (NEDA), the world's largest database of its kind: EIQ's agreement with NEDA provides exclusive 6-year access (with a 10-year option) to novel de-identified health data from >2m echoes from 1.5m Australians, linked to mortality data and collected from 48 cardiology practice centres. The agreement allows EIQ to enhance the data for commercial purposes. The data has been a key resource in training EIQ's AI-backed algorithm and is key to ongoing new product development.

Strategic partnerships supporting rapid commercial roll-out: EIQ has entered several partnerships with specialist distributors (US and Australia) and within the US cardiology community that should support current commercialisation efforts. EIQ has also been selected by a major US cardiovascular-focused healthcare incubator which also facilitates the adoption of novel technologies in US hospitals.

Investment Thesis

Powering clinical decisions with AI, big data: EIQ's exclusive NEDA access provides a unique opportunity to apply its proprietary AI-backed and validated algorithms to improve echo detection of structural heart disease in hard-to-diagnose patients, both for cases considered 'severe' under current guidelines (studies show EIQ's tech improving diagnosis by 72%) and for patients that phenotyping parameters identify as 'at risk' of developing structural heart disease.

Cardiovascular disease increasing: Early diagnosis of CVD is becoming more valuable as an ageing population sees higher prevalence and interventional treatments continue to evolve. Sub-types of valvular disease could provide a multiplier effect to EIQ's technology, given other applications from the NEDA data.

Targeting aortic stenosis – major unmet need for earlier detection: EIQ's first structural heart disease application, AS, is generally characterised by a long latent asymptomatic period before rapid onset of severe symptoms and death. This makes early detection of moderate cases a potential game changer.

Valuation

We value EIQ at $0.77 per share based on DCF methodology and shares on issue of 457.7m.

Risks

EIQ's share price performance is currently most sensitive to product adoption.

Equities Research Australia

Digital Health/Software & Services

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Echo IQ (EIQ) is an ASX-listed med-tech company providing assistive-AI–based cardiac diagnostics/decision support tools to cardiologists. The company's AI-backed, algorithm-based technology leverages exclusive access to big cardiac data stored in the National Echo Database of Australia (NEDA), the world's largest repository/registry of echo data and associated parameters, and data sourced from Australia's National Death Index. EIQ's flagship product, EchoSolv™, is a cloud-based solution for identifying and risk-stratifying patients with aortic stenosis using echocardiogram measurement outputs. EchoSolv™ integrates into clinical practice systems and is designed both as an aortic stenosis audit tool and to support real-time diagnosis. EchoSolv™ is currently available in the US and Australia as a guideline-led decision-support tool.

https://www.echoiq.ai/

Valuation	**A$0.77**
Current price	**A$0.16**
Market cap	**A$73m**
Cash on hand	**A$2.7m (31 March 2023)**

Upcoming Catalysts/Newsflow

Period	
4QFY23	Completion of reader study
1QFY24	FDA submission; contract wins
2QFY24	FDA clearance

Share Price (A$)

Source: FactSet, MST Access.

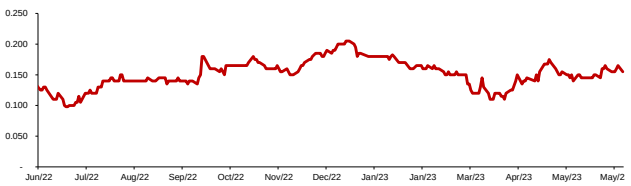
Figure 1: Financial summary

ECHO IQ LIMITED EIQ — **EIQ-AU**

Year end 30 June, AUD unless otherwise noted

MARKET DATA		
Price	**$**	**0.16**
52 week high / low	$	0.1-0.15
Valuation	**$**	**0.77**
Market capitalisation	$m	73.2
Shares on issue (basic)	**m**	457.7
Options / rights	m	145.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**602.7**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY21A	FY22A	FY23E	FY24E	FY25E
Reported NPAT	$m	(3.0)	(6.0)	(5.8)	(1.4)	10.1
Underlying NPAT	**$m**	**(3.0)**	**(6.0)**	**(5.8)**	**(1.4)**	**10.1**
Reported EPS (diluted)	¢	(1.1)	(1.5)	(1.3)	(0.3)	2.2
Underlying EPS (diluted)	**¢**	**(1.1)**	**(1.5)**	**(1.3)**	**(0.3)**	**2.2**
Growth	%		41.7%	-17.6%	-75.7%	-816.9%
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**7.3**
Operating cash flow per share	¢	(0.5)	(0.7)	(1.2)	(0.2)	2.3
Free cash flow per share	¢	(0.9)	(0.8)	(1.2)	(0.2)	2.3
Price to free cash flow per share	**x**	**nm**	**nm**	**nm**	**nm**	**7.0**
FCF Yield	%	nm	nm	nm	nm	14.3%
Dividend	**¢**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**69.4**	**70.8**	**73.2**	**71.8**	**61.4**
EV/EBITDA	x	(47.7)	(24.8)	(21.1)	(102.5)	5.7
EV/EBIT	x	(40.3)	(20.2)	(19.2)	(69.4)	5.9
Price to book (NAV)	x	6.2	8.6	14.0	11.8	4.5
Price to NTA	x	18.9	65.2	(53.4)	(1,061.0)	7.1

KEY RATIOS		FY21A	FY22A	FY23E	FY24E	FY25E
EBITDA margin	%	nm	nm	nm	nm	73.8
EBIT margin	%	nm	nm	nm	nm	71.6
NPAT margin	%	nm	nm	nm	nm	69.0
ROE	%	nm	nm	nm	nm	61.8
ROA	%	nm	nm	nm	nm	53.7
Net tangible assets per share	$	0.0	0.0	(0.0)	(0.0)	0.0
Book value per share	$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	$m	(3.8)	(2.4)	(0.0)	(1.4)	(11.8)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm

DUPONT ANALYSIS		FY21A	FY22A	FY23E	FY24E	FY25E
Net Profit Margin	%	nm	nm	nm	nm	69.0
Asset Turnover	x	0.0	0.0	0.0	0.4	0.8
Return on Assets	%	nm	nm	nm	nm	53.7
Leverage	x	1.1	1.3	1.4	1.4	1.2
Return on Equity	%	nm	nm	nm	nm	61.8

KEY PERFORMANCE INDICATORS	FY21A	FY22A	FY23E	FY24E	FY25E
SaaS contracts secured			1	34	168
# Facilities utilizing EchoSolv™			1	34	168

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Product revenue	$m	0.1	0.0	0.2	0.0	0.0
Operating expenses	$m	(1.7)	(2.0)	(1.6)	(1.9)	(1.9)
EBITDA	$m	(1.6)	(2.0)	(1.5)	(1.8)	(1.8)
EBIT	$m	(1.8)	(2.3)	(1.5)	(2.0)	(2.0)
PBT	$m	(2.8)	(4.6)	(1.6)	(2.2)	(2.2)
Reported NPAT	$m	(2.5)	(4.2)	(1.6)	(2.2)	(2.2)

PROFIT AND LOSS		FY21A	FY22A	FY23E	FY24E	FY25E
Revenue	**$m**	**0.4**	**0.3**	**0.2**	**3.0**	**14.6**
Government revenue	$m	0.3	0.0	0.0	0.0	0.0
Operating expenses	$m	(2.2)	(3.2)	(3.7)	(3.7)	(3.8)
EBITDA	**$m**	**(1.5)**	**(2.9)**	**(3.5)**	**(0.7)**	**10.8**
Depreciation & Amortisation	$m	(0.3)	(0.6)	(0.4)	(0.3)	(0.3)
EBIT	**$m**	**(1.7)**	**(3.5)**	**(3.8)**	**(1.0)**	**10.4**
Interest expense	$m	(0.0)	0.0	0.0	0.0	0.0
Pretax Profit	$m	(3.4)	(6.5)	(6.2)	(1.4)	10.1
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(3.0)**	**(6.0)**	**(5.8)**	**(1.4)**	**10.1**
Weighted average diluted shares	m	276.9	392.8	457.7	457.7	457.7

GROWTH PROFILE		FY21A	FY22A	FY23E	FY24E	FY25E
Revenue	%	(35.0)	(43.2)	(20.5)	(50.0)	0.0
EBITDA	%	46.3	96.6	21.3	(79.8)	(1,635.4)
EBIT	%	53.4	103.0	9.1	(72.9)	(1,109.5)
Reported NPAT	%	11.6	100.1	(3.7)	(75.7)	(816.9)

BALANCE SHEET		FY21A	FY22A	FY23E	FY24E	FY25E
Cash	$m	3.8	2.4	0.0	1.4	11.8
Receivables	$m	0.5	0.3	0.3	0.4	0.4
Other	$m	0.0	0.5	0.5	0.5	0.5
Current assets	**$m**	**4.3**	**3.2**	**0.9**	**2.2**	**12.7**
PPE	$m	0.0	0.0	0.1	0.1	0.1
Intangible assets and goodwill	$m	6.6	7.0	6.6	6.3	6.0
Other	$m	0.0	0.0	0.0	0.0	0.0
Non current assets	**$m**	**6.7**	**7.0**	**6.7**	**6.4**	**6.1**
Total assets	**$m**	**10.9**	**10.2**	**7.5**	**8.6**	**18.8**
Trade and other payables	$m	0.5	1.7	1.8	1.9	2.0
Lease liabilities	$m	0.0	0.1	0.1	0.1	0.1
Other	$m	0.6	0.4	0.4	0.4	0.4
Current liabilities	**$m**	**1.1**	**2.2**	**2.3**	**2.4**	**2.5**
Lease liabilities	$m	0.0	0.0	0.0	0.0	0.0
Other liability	$m	0.0	0.0	0.0	0.0	0.0
Non current liabilities	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Total liabilities	**$m**	**1.1**	**2.2**	**2.3**	**2.4**	**2.5**
Net assets	**$m**	**9.8**	**8.0**	**5.2**	**6.2**	**16.3**
Share capital	$m	27.9	30.4	30.4	30.4	30.4
Retained earnings	$m	(21.7)	(27.7)	(30.5)	(29.5)	(19.4)
Other	$m	3.6	5.3	5.3	5.3	5.3
Total equity	**$m**	**9.8**	**8.0**	**5.2**	**6.2**	**16.3**

CASH FLOW		FY21A	FY22A	FY23E	FY24E	FY25E
Net loss for period	**$m**	**(3.0)**	**(6.0)**	**(5.8)**	**(1.4)**	**10.1**
Depreciation & Amortisation	$m	(0.3)	(0.6)	(0.4)	(0.3)	(0.3)
Changes in working capital	$m	(0.3)	(0.0)	0.1	0.1	0.1
Other	$m	2.1	4.1	0.7	0.7	0.6
Operating cash flow	**$m**	**(1.4)**	**(2.6)**	**(5.4)**	**(1.0)**	**10.5**
Payments for PPE	$m	(1.0)	(0.4)	(0.0)	(0.0)	(0.0)
Other	$m	0.0	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**(1.0)**	**(0.4)**	**(0.0)**	**(0.0)**	**(0.0)**
Equity	$m	2.5	0.0	0.0	0.0	0.0
Lease liability payments	$m	0.4	1.5	3.0	2.4	0.0
Other	$m	(0.2)	0.0	0.0	0.0	0.0
Financing cash flow	**$m**	**2.8**	**1.5**	**3.0**	**2.4**	**0.0**
Cash year end	**$m**	**3.8**	**2.4**	**0.0**	**1.4**	**11.8**
Free cash flow	**$m**	**(2.4)**	**(3.0)**	**(5.4)**	**(1.0)**	**10.4**

Source: Company reports, MST Access estimates

Investment Thesis: Harnessing AI in Cardiology

Company profile: enhancing diagnosis of structural heart disease with artificial intelligence, focusing on aortic stenosis

Echo IQ (EIQ) is an ASX-listed med-tech company with proprietary artificial intelligence (AI) software to support detection by cardiologists of structural heart disease. The software has been developed and validated using big cardiac data sourced from the world's largest and most extensive echo database, National Echo Database of Australia (NEDA). EIQ's first product application is focusing on detection of aortic stenosis (AS), a disease that is common but difficult to diagnose, with cases often being missed.

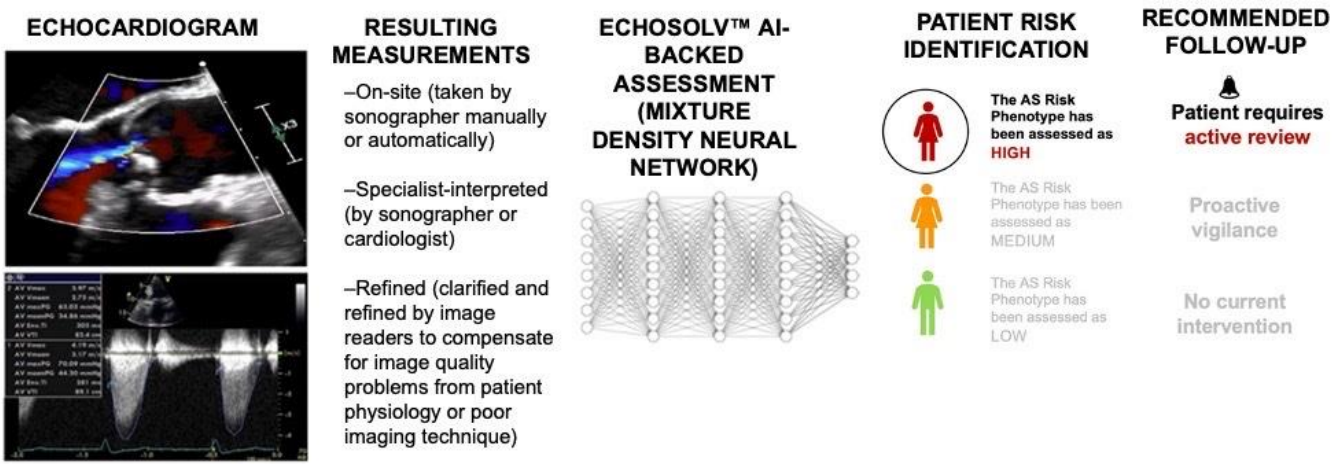
The company was formed through the acquisition of Alerte Echo IQ (ECHO IQ) (for A$1m cash and 30m shares in HWH @5c) by Houston We Have (HWH:AX) in May 2021, which later rebranded as Echo IQ (EIQ:AX) in December 2021.

EIQ's product is designed to enhance the diagnosis of severe AS using measurement outputs of echo diagrams to: (1) support detection of severe AS as defined by AHA guidelines; and (2) stratify patients at risk of AS to support clinical decisions in the management of these patients.

Product and platform: EchoSolv™ – helping to identify AS with the backing of exclusive database access

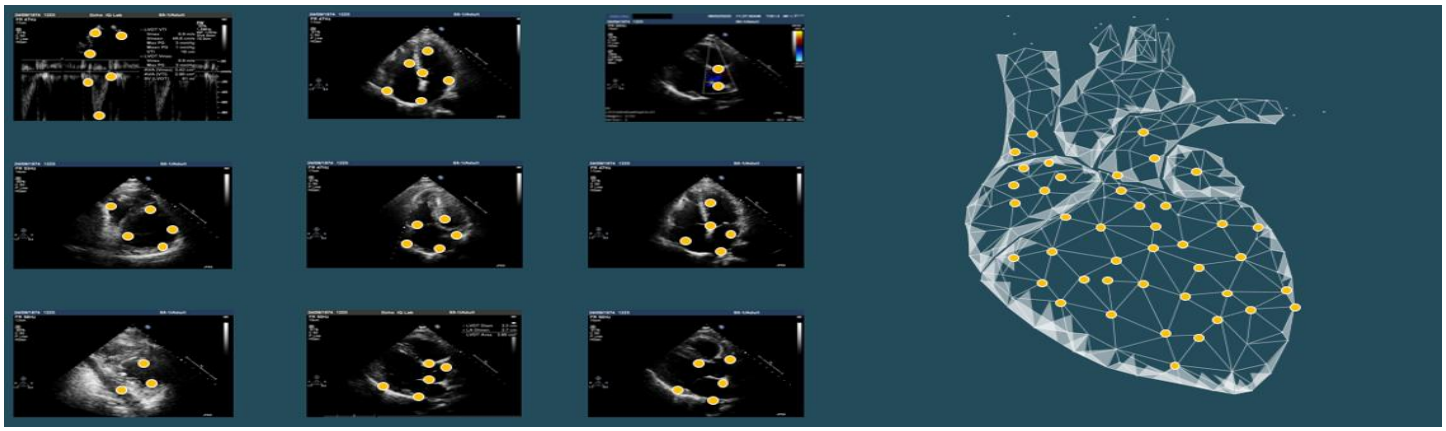
The company's first commercially available product, cloud-based decision-support software EchoSolv™, uses AI to assess echo measurements and assists cardiologists to identify guideline-defined AS. EIQ's platform leverages its 15-year exclusive access to NEDA, which contains 2m echocardiographic outputs on 1.5m individuals. The software then uses a modified mixture density network, a deep learning methodology which mimics the nuanced thinking of the human brain (see Flagship Product section for an explanation of this concept), to train, interrogate and validate the AI algorithm.

Figure 2: The EchoSolv™ workflow: how EIQ's technology will help cardiologists identify more at-risk patients



Source: EIQ, MST Access.

Figure 3: EchoSolv™ processes a multitude of measurements from echoes in order to generate its stratified risk assessment



Source: EIQ.

Benefits: reliability, objectivity, nuance

Cardiologists review up to 100 echocardiographic images and about 60 echocardiographic measurements per patient, manually scanning for multiple common problems as well as rarer conditions. Benefits of review by a cardiologist working with EchoSolv™ (vs. review by a cardiologist only) include:

- added reliability: in 2 studies, the software identified 100% of the guideline-defined cases of AS (AUCROC of 0.986)[1]
- removal of unconscious bias (for example, gender bias; clinicians being reluctant to diagnose a condition that may necessitate a dramatic intervention) when interpreting the images
- detection and stratification of AS risk into the categories of low, medium-moderate (mortality of those untreated = 56% at 5 years), and severe (mortality of those untreated = 68% at 5 years).
- zero variability in diagnosis
- analysis performed in less than 3 seconds.

Commercial strategy: focusing on aortic stenosis in the short term

EIQ has two versions of its EchoSolv™ software. Version 1 (the 'lite' version) is available for immediate commercialisation, as it does not require FDA clearance. This version identifies patients who meet the current guidelines for severe AS. Version 2 (the 'pro' version) will be subject to FDA 510(k) clearance. This version will phenotype patients to identify their risk of AS across the categories of mild, moderate and severe. (Note that while the 'pro' version will unlock substantial additional revenue and reimbursement opportunities, both versions of the product are powerful, AI-backed platforms with research-validated ability to enhance diagnosis of AS.)

Near-term revenue opportunities: EIQ has identified several industry segments to pursue commercial opportunities including valve manufacturers, hardware producers of echo machines and reporting software, specialist cardiologists/clinics, hospitals, the health insurance sector and general practitioners.

Longer-term growth opportunities: The company is also examining the application of its AI technology to other forms of cardiac and structural heart disease. These include multiple CV applications (mitral valve regurgitation, tricuspid regurgitation, both systolic and diastolic heart failure) which provide a potential multiplier effect for EIQ.

Regulatory clearance: FDA 510(k) key to value creation

Potential FDA 510(k) clearance opens the door to the launch of the EchoSolv™ 'pro' version (the second version of its product, which will enable phenotyping and risk-stratifying at-risk patients – which would open up reimbursements and materially boost revenue). The timeline to this anticipated clearance is as follows:

- 4Q2022: EIQ held its pre-submission meeting with the FDA: achieved acceptance of predicate; was recommended reader study
- 1Q2023: reader study set up, with study design accepted by FDA and sites identified
- 2Q2023: reader study runs
- 3Q2023: 510(k) submission
- 4Q2023: 510(k) clearance

Corporate history and recent events

May 2021 – acquisition of Echo IQ by HWH: HWH acquired 100% of the shares in Alerte Echo IQ (ECHO IQ) for a consideration of 30m fully paid ordinary HWH shares to Echo IQ shareholders and a $1m cash payment.

Mid-2022 – US regulatory and commercial position strengthened: EIQ lodged its patent (with international extensions to its IP protections planned for 2023).

EIQ was selected as one of 5 participants in the US-based HeartX accelerator program (incubator), which provides the company with additional equity funding of $150,000, as well as access to hospital pilot projects and clinical trials, supporting its FDA application.

Late 2002 – EchoSolv™ launched in the US: EIQ launched its AS platform for version 1 of the product, which can detect severe AS in line with AHA guidelines.

4Q2022–1Q2023 – key clinical validation achieved with 100% success rate: In research conducted at several hospitals – Beth Israel Deaconess (Boston) and St Vincent's (Melbourne and Sydney) –

[1] Phenotype ('pro') version of EchoSolv™ (see Flagship Product section for more information on the versions).

cardiologists using EchoSolv™ were able to identify 100% of cases of severe AS, a 72% improvement on the results achieved by cardiologists using only manual review of echocardiograms.

2Q2023 – first revenues: EIQ achieved its first revenues with its first commercial deployment of EchoSolv™ in Australia to a private cardiology practice under a SaaS agreement (details undisclosed). EchoSolv™ will initially be used in audit mode by the practice to review echocardiographic measurements obtained over a 12-month period and integrated into the practice's reporting systems, for use in real-time analysis.

Valuation: A$0.77 per share, representing significant upside

We value EIQ at A$354m, which equates to A$0.77 per share (or A$0.59 per share, fully diluted), using DCF methodology (assumptions listed on page 18).

Figure 4: Simplified base-case DCF valuation and key metrics (A$)

		Jun-23	Jun-24	Jun-25	Jun-26	Jun-27	Jun-28	Jun-29	Jun-30	Jun-31	Jun-32	Jun-33
		2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Free cash flow	A$m	**(4.1)**	**(1.3)**	**10.2**	**34.2**	**37.3**	**57.5**	**57.4**	**57.4**	**57.4**	**57.3**	**57.3**
Discount coefficient	years		1.1	2.1	3.1	4.1	5.1	6.1	7.1	8.1	9.1	10.1
Discounted cash flow	A$m		**(1.2)**	**8.0**	**23.7**	**23.0**	**31.5**	**28.0**	**24.9**	**22.1**	**19.6**	**17.4**

Sum of discount streams	A$m	197.0	**CAPM**		
Terminal growth	%	1.0%	Risk free rate	%	5.0%
Future value into perpetuity	A$m	503.3	Equity beta	x	1.25
NPV of terminal value	A$m	154.6	Equity risk premium	%	6.0%
PV of cash flows	A$m	351.6	Cost of equity	%	12.5%
PLUS: Value of investments	A$m	-	Debt	%	0%
LESS: Net debt	A$m	(2.6)	Equity	%	100%
Equity value	**A$m**	**354.3**	Interest rate	%	0.0%
Ordinary shares	m	457.7	Tax rate	%	30%
Value per share	**A$**	**0.77**	WACC	%	12.5%

Source: MST Access.

Potential near-term catalysts

We expect to see share price upside over the next 12 months given anticipated positive news flow on a number of fronts.

Progress towards regulatory clearance, which would unlock adoption and reimbursement

Reader study (a critical step in order to finalise submission to FDA): completion of enrolment (4QFY23) and completion of study (1QFY24: expected late July 2023)

1QFY24 – FDA submission to be filed

2QFY24 – FDA clearance (anticipated in December 2023)

Contract wins, which will provide near-term revenue and longer-term client relationships

1QFY24 – Hydrix SaaS contract wins in smaller clinical practices

1QFY24 – Cassling SaaS contract wins in ASCs, hospitals and directly with individual cardiologists

Increased awareness of the product

2QFY24 – Major interventional cardiologist conference, 'Cardiovascular Transforum', hosted by MedAxiom (October 2023)

Risks to our view

EIQ is operating in a relatively new and rapidly evolving segment of digital health. Commercialisation is still at an early stage and therefore exposes investors to various risks related to competition, customer mix, resource and capital allocation, product development, regulatory clearance, and reimbursement.

EIQ's proprietary AI algorithms have been trained using echocardiogram data from NEDA for the first application of AS. As such, the company's new product development is vulnerable to continuing integrity of the NEDA data and the risk of cybersecurity.

Company Outlook: Leveraging Cardiac Big Data to Support Diagnosis of Structural Heart Disease

Echo IQ (EIQ) is an ASX-listed med-tech company that uses artificial intelligence (AI)–backed algorithms, in conjunction with exclusive access to the National Echo Database Australia (NEDA) – the largest echocardiogram database in the world, according to NEDA – to identify patients both at risk of and treatable for aortic stenosis (AS), one of the most common forms of heart disease (and most common heart valve disease). Its flagship EchoSolv™ technology enables the tracking of moderate AS and can help identify undiagnosed severe disease, supporting cardiologists as they work to treat patients in a timely manner and save lives while reducing the healthcare cost burden and productivity losses.

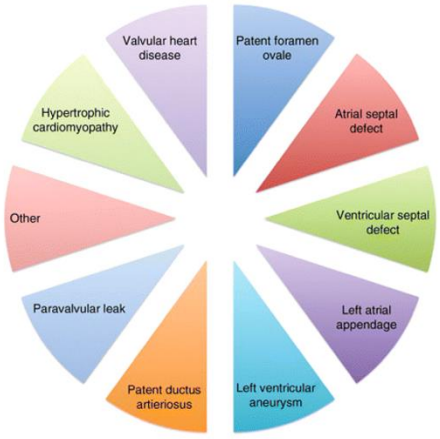
Market opportunity: heart valve disease

Valve disease: a serious and growing problem for millions as the population ages

Structural heart disease refers to non-coronary (valves, walls, or chambers) cardiovascular diseases and related interventions[2] including valvular heart disease – an area of intense clinical interest given the ageing population and recent research findings. The CDC has stated that 2.5% of the US population has valvular heart disease, with this number rising to 30% of people aged 80 and over.[3]

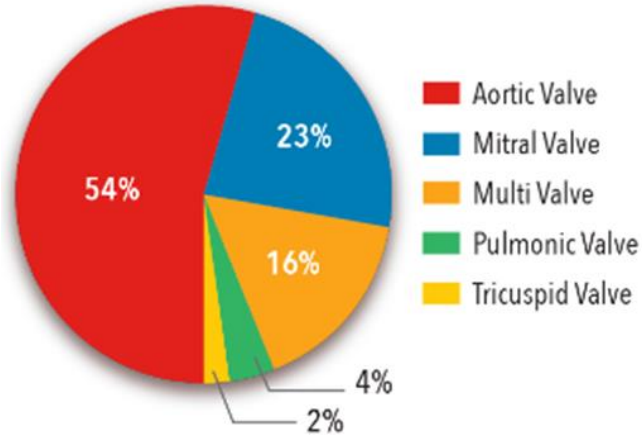
Access to echocardiography, the modality targeted by EIQ's technology platform, is a vital component in managing heart valve disease in the community. *Our Hidden Ageing: Time to listen to the heart* (report published by Baker Heart and Diabetes Institute, 2017) stated that 500,000–600,000 Australians were living with heart valve disease in 2021, including an estimated 254,000 undiagnosed cases (estimated to grow to 336,000 in 2031 and 435,000 in 2051). Valve disease is often asymptomatic and thus unrecognised until an urgent intervention is needed due to a crisis (heart failure or atrial fibrillation). *Our Hidden Ageing* suggests that the common symptoms of valve disease, especially exercise intolerance, are often misattributed to 'old age'. Timely diagnosis is based on awareness and clinical examination.

Figure 5: Range of structural heart disease



Source: Defining structural heart disease in the adult patient: current scope, inherent challenges and future directions: Steinberg et al (2010).

Figure 6: Aortic valve procedures are most common by far



Source: New York–Presbyterian.

EIQ's focus: aortic stenosis, a common and serious valve disease

Poor outcomes for patients with severe AS are well known… AS is the most common acquired heart valve disease requiring active clinical intervention (see Figure 6 for percentage of valve procedures relating to the aortic valve) and one of the most common forms of heart valve disease in older people (see box on p. 8). It is associated with high risks to life if not identified and treated quickly. According to the *British Medical Journal*, after symptoms appear, patients with severe AS have a survival rate as low as 50% at 2 years – and 20% at 5 years – without aortic valve replacement. However, studies suggest that 70% of severe AS patients are either misdiagnosed or not identified.

[2] Defining structural heart disease in the adult patient: current scope, inherent challenges and future directions: Steinberg et al (2010)

[3] https://www.cdc.gov/heartdisease/valvular_disease.htm#:~:text=About%202.5%25%20of%20the%20U.S.,1943%20have%20valvular%20heart%20disease.

…but another AS opportunity has emerged with moderate cases. New research[4] highlights poor long-term survival rates in patients with moderate AS. Recently reported NEDA study data[5] suggests that even mild to moderate AS is associated with high levels of mortality if untreated, with 5-year mortality of untreated asymptomatic patients of 56% within the phenotype risk assessment of 'moderate' vs. 68% for those in the 'severe' category.

EIQ sees a huge unmet need for earlier AS detection. EIQ is leveraging its access to NEDA to develop applications across several heart valve diseases, commencing with aortic stenosis (AS). EIQ chose AS for the first application of its AI model to echocardiography, in light of the significant opportunity represented by the mortality statistics in this disease to improve patient outcomes with earlier detection and intervention at an earlier stage. AS is a strong first indication for EIQ's technology, because:

- severe AS is highly prevalent in the population (see box, next page)
- the treatment landscape is evolving, with earlier interventions being made possible, improving patient outcomes and easing the burden to the healthcare system
- less invasive interventions, e.g. non-surgical valve replacement procedure Transcatheter Aortic Valve Implantation (TAVI), have major productivity benefits – *Our Hidden Ageing* suggests that such procedures for people aged 65+ years could potentially prevent productivity losses of up to $117m per annum by reducing rehabilitation time and lowering the risk of eventual heart failure.

Current clinical landscape for aortic stenosis

Echocardiography is the key clinical tool for diagnosing structural valve disease. Echocardiography is one of the most used, non-invasive methods for looking at cardiac anatomy (see Figure 7 for information on the basics of echocardiography and other heart-scanning modalities). Echocardiography is used to provide thin cross-sections of cardiac structures, including left and right atria, left and right ventricles, valves, and associated valvular structures.

Cardiologist review of echoes is the key diagnostic tool – but many cases are missed. Despite being so common, AS is difficult to diagnose. To assess a patient, cardiologists review up to 100 echo images and about 60 echo measurements, manually scanning for common problems and rarer conditions. The diagnostic process can be prone to human error and unconscious bias. Overall, 1 in 3 malpractice cases in the US resulting in death/permanent disability stem from inaccurate or delayed diagnosis.

Figure 7: Overview of echocardiography and other heart scanning modalities

Modality	Output	Method	Pros (+) and cons (–)
Echocardiogram (also called 'echo')	A picture of the overall structure of the heart, its valves and attached structures	Transducer placed on patient's chest which transmits ultrasound waves into the chest Echoes from soundwaves turned into picture	+Detailed picture +No radiation exposure +Standard transthoracic echo is non-invasive +Quick and reliable –Less detail than cardiac MRI
Electrocardiogram (also called 'ECG' or 'EKG')	A graph of the heart's electrical activity	Sensors (electrodes – sticky patches with wires) are attached to patient's chest, arms and legs Sensors measure and record heart's electrical signals, create graph	+No radiation exposure +Non-invasive +Can diagnose arrhythmias –No picture – output is graph only
Cardiac computerised tomography (CT) scan	Images of heart which can be combined for composite 3D image to assess (1) calcium in heart's arteries (coronary calcium scan) or (2) fatty plaque in arteries that bring blood to heart (coronary angiogram)	In some cases, patient takes medicine to slow heart rate before procedure Electrodes are placed on the chest to measure heart's electrical activity Thin x-ray beam rotates around patient's body inside the scanner to create the image	+Non-invasive +3D image can be created –Exposure to radiation –Dye needs to be injected before coronary angiogram (can occasionally cause allergic reactions or kidney problems)
Cardiac magnetic resonance imaging (MRI)	Images of the heart Can also create video of the heart as it pumps blood	Patient lies on bed with leads on their chest to measure heartbeat and detectors rested on the chest Bed moves into tunnel-like MRI machine Humming and knocking noises occur during the scan	+No radiation exposure +Non-invasive +Measures pumping of blood through heart – can calculate blood flow +Detailed 3D image and video –Unsuitable for patients with (1) metal in their body (eg pacemaker, artificial heart valves) or (2) severe claustrophobia –Can require contrast dye injection (can occasionally cause allergic reactions or kidney problems)

Source: Baptist Health, Cleveland Clinic, Mayo Clinic, Johns Hopkins Medicine, Medlineplus.gov, St Vincent's Hospital, Inside Radiology, Stokes MB, Roberts-Thomson R. 'The role of cardiac imaging in clinical practice.' Aust Prescr. 2017 Aug;40(4):151-155.

[4] Poor Long-Term Survival in Patients With Moderate Aortic Stenosis: G. Strange et al (2019)

[5] Uncovering the treatable burden of severe aortic stenosis in Australia: current and future projections within an ageing population: G.Strange et al (2021)

Aortic valve stenosis: an emerging epidemic driven by an ageing population

What is aortic stenosis, and who typically suffers from it?

Aortic valve stenosis or aortic stenosis (AS) is a slow progressive disease affecting the aortic valve, which separates the heart's left ventricle (chamber) from the body's main artery, the aorta, and allows blood to be forced into the arteries from the ventricles while preventing it from flowing back into the ventricles.

AS is characterised by narrowing of the aortic valve, which makes it difficult for the heart to pump blood from the left ventricle into the aorta. This can cause the left ventricle to thicken and enlarge, reducing cardiac efficiency and weakening overall heart function.

AS is the most common and serious of valve diseases, with prevalence estimated at:

- around 3% of the population aged 60–74 years
- around 13% for those over 75 years (about 1 in 8 people).

What are the risk factors for this disease?

The most common cause is the build-up of calcium deposits over time, and therefore the disease is highly correlated with ageing. Although AS can be caused by infections that affect the heart (such as rheumatic fever), congenital heart defects, history of radiation therapy to the chest, chronic kidney disease, and cardiovascular risk factors (diabetes, high cholesterol, high blood pressure).

What are the symptoms of aortic stenosis?

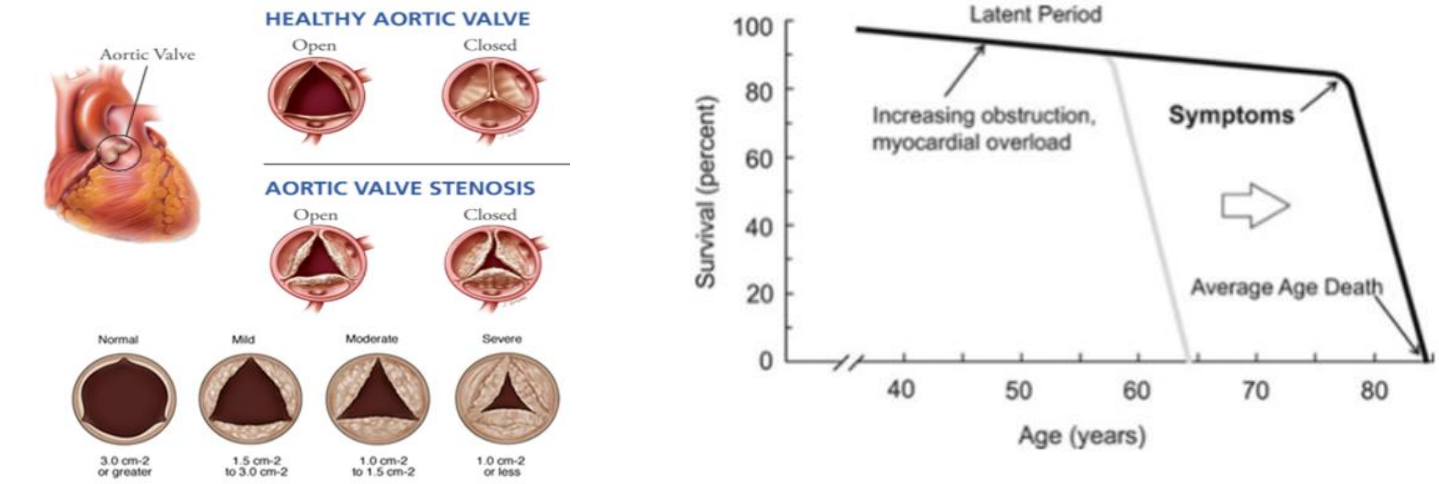
Progressive narrowing of the aortic valve from calcification of the valve leaflets (see Figure 8) leads to inadequate cardiac output, decreased exercise capacity, heart failure and death from cardiovascular causes. Given its slow progression, AS patients can be asymptomatic for decades. In fact, many people are unaware they have the condition or may be told they have a heart murmur during a routine check-up.

However, mortality is more than 60% at 2 years once patients develop symptoms. Symptoms of severe AS can include dizziness, fainting, angina (chest pain/tightness with activity), fatigue, shortness of breath, irregular heartbeat, heart palpitations, and swelling in the legs.

How is aortic stenosis diagnosed?

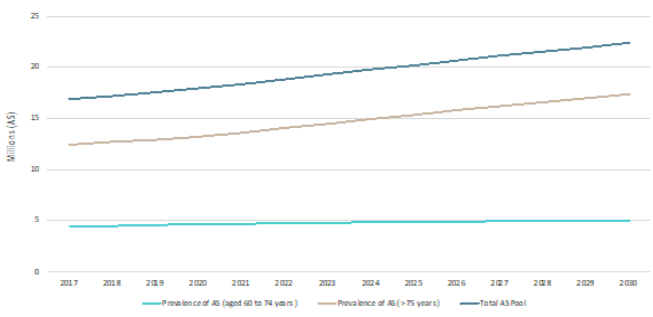
Diagnosis of AS almost always relies on a transthoracic echocardiogram, which is an ultrasound of the heart. Reviewing cardiologists evaluate a series of measurements (of various heart structures including heart valves) to make a determination. Additional tests may include CT scans and ECG, but echocardiogram remains the gold standard in AS diagnosis.

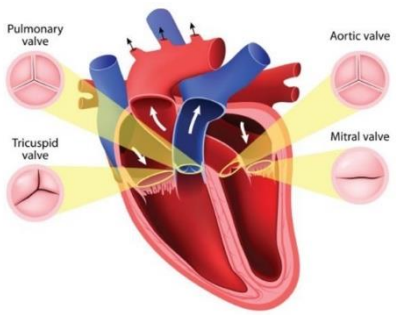
Figure 8: Inside a narrowed valve with aortic stenosis (left); this disease can quickly kill after becoming symptomatic (right)



Source: https://intermountainhealthcare.org/services/heart-care/conditions/aortic-valve-stenosis (left), American Heart Association (right).

Figure 9: Growing prevalence of AS given ageing population





Source: United Nations population forecasts; MST Access estimates.

Flagship Product:
EchoSolv™ Clinical Decision Support Platform

EIQ has developed two versions of EchoSolv™. The first version ('lite') is currently available, as it does not require FDA clearance. The 'lite' version works within the current 'severe AS' guidelines to identify cases that conform to these guidelines. The second version ('pro') will be ready to commercialise after FDA 510(k) clearance is obtained. This version phenotypes patients by stratifying them into a risk category. Both versions can be used clinically to review past patients or to cross-check scans in real time.

The goal – enhancing disease diagnosis with echocardiography

The company's EchoSolv™ software assesses echocardiograms, the most common diagnostic/imaging modality for identifying AS, using a range of echocardiographic measurements and applies a combination of machine learning and current medical guideline recommendations to provide a probability of the phenotype (risk profile) of severe AS.

How it works – big data + AI-backed algorithms

EchoSolv™ uses AI-driven algorithms and big data. The software has been trained using labelled input data (echo measurements, or 'labels') and programmed processes to derive relationships between the 'labels'. The derived relationships are then used to predict how new input data would be labelled, which becomes a prediction, diagnosis or recommendation for the clinician in an AI/ML-enabled CDS tool.

Exclusive NEDA big data access: a huge competitive advantage

The National Echo Database Australia (NEDA) is a database that brings together health information from adults who have undergone an echo at a participating hospital throughout Australia. It is the largest echo database of its type, linked to mortality outcomes, in the world. NEDA was set up in 2018 to support research into pulmonary hypertension with the intention of being a not-for-profit research organisation. The scope of the database was soon expanded to consider any disease/condition involving an echo.

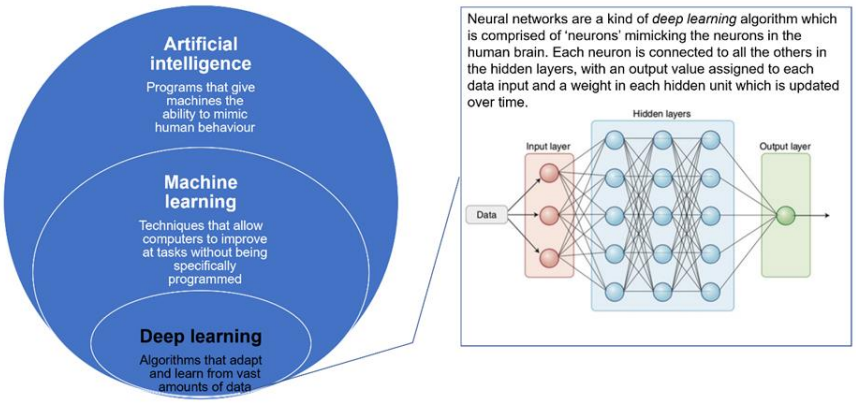
NEDA extracts data from digital echo laboratories across Australia and combines detailed cardiac measurement data (but not images) into a central, standardised database. This data is correlated against the National Death Index to look at threshold of mortality associated with multiple different diseases. Given the focus on echoes, diseases directly affecting the heart are a natural area of clinical applications.

EIQ has an exclusive agreement in place which runs for another 5 years with a further 10-year option to renew at EIQ's discretion. This exclusive agreement protects EIQ's first-mover advantage by ensuring that competitors do not have access to this rich store of data in order to train competing algorithms.

AI-backed algorithm: developed by a mixture density neural network for nuanced diagnostic guidance

EIQ used a 'mixture density neural network' to develop its artificial intelligence (AI) model, analysing large volumes of echo measurements to identify patterns and relationships in the data indicative of AS. The 'mixture density' aspect of this network refers to its ability to estimate a probability distribution for different diseases or conditions based on the input heart data. Instead of providing a simple yes or no answer (e.g., that a patient does or does not have a disease), mixture density neural networks provide a probability distribution that assigns a likelihood to each possible outcome (see Figure 10).

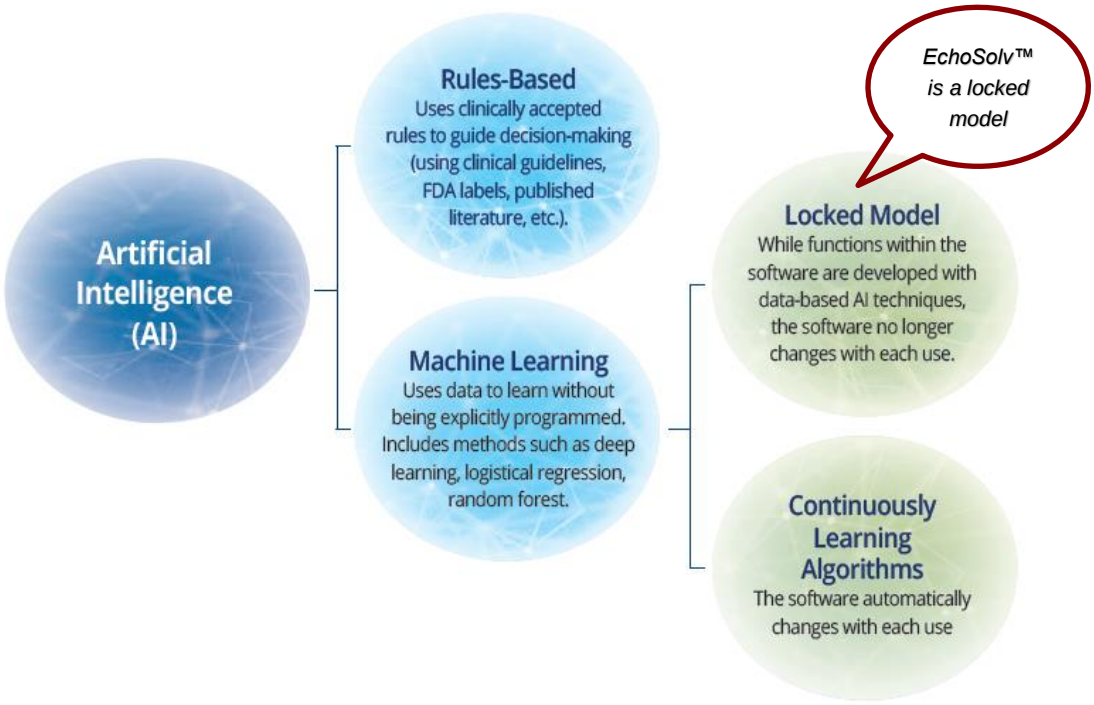
Figure 10: 'Deep learning'–level artifical intelligence, powered by a substantial volume of big data, can create sophisticated algorithms that provide nuanced diagnostic guidance



Source: MST Access, adapted from: LEFT – 'Artificial intelligence and the cardiologist: what you need to know for 2020', Heart, March 2020, Vol 106, No 5, pp. 399–400; and RIGHT – 'Artificial Intelligent [sic] in Healthcare', Meiliana A et al, The Indonesian Biomedical Journal, 2019, 11(2): 125-35.

Once a model is developed, it can continue to learn or be fine-tuned by incorporating new data (learning data). These changes can be made automatically each time a new labelled example is received (continuously learning algorithms) or the labelled examples can be stored for periodic updating of the tool (locked models): see Figure 11. Note that EchoSolv™ is a locked model – historically, the FDA has not wanted to permit the use of devices whose algorithm keeps changing in ways it does not understand.

Figure 11: Breakdown of rules-based AI and machine learning



Source: Evaluating AI-Enabled Clinical Decision and Diagnostic Support Tools Using Real-World Data: healthpolicy.duke.edu.

The value proposition – benefits for organisations, clinicians, patients

EchoSolv™ delivers benefits at both an organisational and indvidual physician level, aimed at enhancing diagnosis and improving outcomes for patients. Figure 12 details the value proposition at the healthcare facility and physician level.

Early detection

In general, a mixture density neural network can detect diseases or health conditions at an early stage when symptoms may not be obvious. By identifying potential issues early on, doctors can intervene and provide appropriate treatments or preventive measures to improve patient outcomes.

Personalised medicine

The network takes into account various factors from the heart data to provide a tailored assessment. It considers the unique characteristics of each patient, such as age, gender, medical history, and current health status. This personalised approach helps doctors make more accurate diagnoses and develop targeted treatment plans.

Specifically, the company has used the mixture density neural network to identify the AS phenotype in patients. EIQ trained the model using the NEDA dataset to look for patients specifically with AS phenotypical characteristics and verified this against NEDA's mortality risk data, making the model highly capable of stratifying patients at varying risks of death from severe AS. The model's ability to assess probability makes it useful for working with large or smaller datasets (narrow input data).

Improved accuracy

Traditional diagnostic methods often rely on human interpretation, which can be prone to errors and subjectivity. The mixture density neural network, on the other hand, utilises advanced algorithms to analyse vast amounts of data, leading to more objective, consistent and accurate results.

Speed, efficiency and improved workflow

The network can process heart data quickly, allowing for rapid diagnosis and decision-making. This saves valuable time for both patients and healthcare providers, enabling timely interventions and reducing waiting times for diagnosis. The software automatically analyses echocardiographic measurements in under 3 seconds to improve the detection and diagnosis of patients at high risk of structural heart disease.

Figure 12: EchoSolv™ value proposition

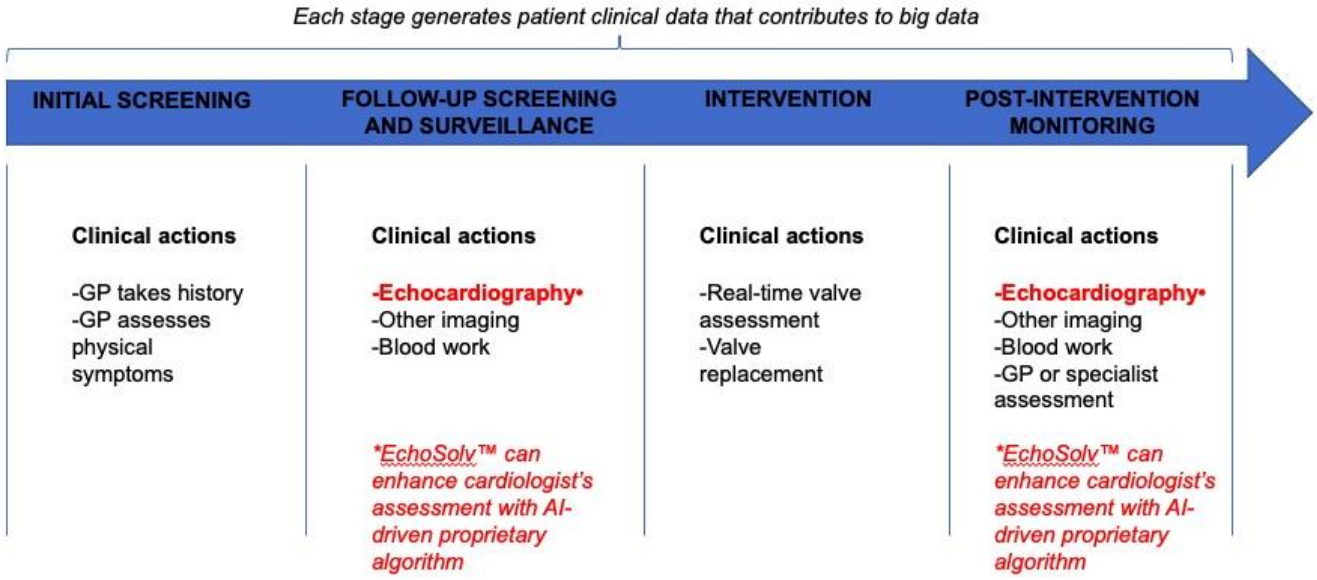
Healthcare facility		Physician	
Improves workflow	Evidence-based clinical decision support improves workflow and saves time	Automates diagnosis of various cardiac conditions	Increases precision and accuracy, providing physician with increased time for direct patient care
			Clear call to action with automated prompts to physician
Improved quality outcomes	Echo Audit flags in-guideline patients that may have previously been misdiagnosed or underdiagnosed	Improved accuracy	Detects 100% of in-guideline patients
	Ensures equitable and standardized care across geography, race, age and gender		Better informed decision with zero variability in diagnosis
Increased provider productivity	More appropriate patients identified for procedures	Accelerate diagnosis	Triage tool for earlier disease detection of at-risk patients with inclusion of phenotype population
	Increased procedure revenue		Results available in under 3 seconds
Scalable	AI connects seamlessly through the cloud with HIPAA & SOC2 compliant security	Trusted	Validated by over 200M echo datapoints in over 1.8M individual patients
	Cloud-based solutions allow for easy updates and ensure latest innovations		

Source: EIQ.

How it fits into workflow – 'software as a medical device'

EchoSolv™ is an AI-enabled clinical decision and diagnostic support (CDS) tool, designed to enhance heart disease diagnosis whenever echocardiographic measurements are involved. Given echocardiography is the most frequently used cardiovascular diagnostic test after electrocardiography and chest X-ray, there are multitude of opportunities for EchoSolv™ to be added into the mix.

Figure 13: Clinical decision support for whenever echocardiography is used



Source: EIQ, MST Access.

The technology stack – key components that make the system work

Infrastructure

EIQ uses Amazon Web Services (AWS) to host its offering globally. While some data relating to the management of the algorithm is synchronised globally for maximum resilience, all health data for North America is locked to the company's US data centres. Similarly, all health data for Asia Pacific and Middle East clinics is locked to Australian data centres.

AI frameworks

EIQ's AI is developed in Python, using a TensorFlow model, and is deployed to AWS Lambda.

Compliance – cybersecurity and anonymisation

AWS ensures EchoSolv™ can be offered in a highly compliant infrastructure environment, meeting multiple global best-in-class security standards.

EIQ as a service provider has undergone independent auditing and certification to meet compliance with SOC2 Type II requirements and complies with the Health Insurance Portability and Accountability Act (HIPAA) Safe Harbour Provision guidelines, including the protection of all names, dates and locations.

Figure 14: Key components of EIQ's technology stack

Source: EIQ.

Customer onboarding – adding EchoSolv™ to clinical workflows

EIQ has designed a Fast Track implementation process to facilitate embedding of its software into existing hardware across different clinical settings and data formats. Measurements from a patient's echocardiogram are transferred to the secure EchoSolv™ cloud service where they are assessed using EIQ's AI models. The results of high-, medium- and low-risk patients can be accessed on demand using a web application available on the desktop and mobile.

The process is slightly different depending on whether the customer uses a DICOM®-compliant picture archiving and communication system (PACS) or reporting solution (see Figure 15). A PACS is an electronic medical image management system, and DICOM® is the international standard to transmit, store, retrieve, print, process, and display medical imaging information.

For customers using a PACS, new echoes are transmitted to the PACS, which then automatically transfers echo measurement data to EchoSolv™. All communication occurs over HTTPS to static IP addresses, allowing the clinical teams to appropriately secure network access.

If clinic does not use a DICOM-compliant PACS or reporting solution, EIQ can still automate transfer using Echo IQ Connect. The clinic's echo devices can be configured to use Echo IQ Connect as a DICOM-compliant SR server [6]. This allows sonographers to send measurements manually or automatically to EchoSolv™ on completion of an echocardiogram, direct from the echo device.

[6] Structured report (SR) files are special type of DICOM files designed for exchanging clinical information and findings.

Figure 15: Clinical workflow integration for clients who (1) use a DICOM-compliant PACS or reporting solution (top) or (2) do not use a DICOM-compliant PACS or reporting solution (bottom)

Source: EIQ.

Clinical validation

Several studies have validated the EchoSolv™ technology, with results that support its use in helping clinicians diagnose AS early and accurately.

Study site: Beth Israel Deaconess Medical Center (Harvard Medical School)

Study details

Completed November 2022; study size: 31,141

The study retrospectively analysed patient records in order to evaluate EIQ's technology in detecting individuals with severe AS as well as those with increased risk of death from the disease in a North American population.

Key findings

- EchoSolv™ identified 100% of patients with guideline-defined AS, equal to 5% of patients undergoing echocardiography at BIDMC
- EchoSolv™ identified an additional cohort, similar in size, at high risk of mortality despite not meeting current treatment guidelines
- 3/4 of patients with increased risk of death from AS identified by EchoSolv™ had not received treatment.

Research: International Cohort Study

Publication details

Published in JASE (*Journal of the American Society of Echocardiography*), January 2023; study size: 248,646 (US and Australia)

In the paper 'Risk for Mortality with Increasingly Severe Aortic Stenosis: An International Cohort Study', authors (G. Strange et al) evaluated the risk of progressive AS in two large parallel cohorts with respect to risk of mortality in patients.

Key findings

The distribution of AS severity was similar in both the US and Australian cohorts. Despite different healthcare systems, similar patterns of mortality existed linked to increased severe AS, supporting the need to develop and apply more proactive surveillance strategies in this high-risk population.

Study sites: St. Vincent's Hospitals, Melbourne and Sydney

Study details

Completed 2022–2023; study sizes: 8,257 and 9,189

This study was designed to test the effectiveness of AI-backed software solution EchoSolv™ in identifying patients with, and at risk of dying from, AS, consistent with current guidelines. The study was fully funded by Edwards Lifesciences (NYSE: EW) and was conducted in conjunction with NEDA.

Key findings

On 19 April 2023, EIQ announced that the final results from the study supported the use of EchoSolv™ as both an audit tool and real-time clinical decision support tool.

- EchoSolv™ identified an additional cohort, 72% more patients, at high risk of mortality.
- EchoSolv™ identified 100% of patients with guideline-defined AS, equal to 4% of the study population.
- Women were 66% less likely to have been accurately diagnosed than men, but EchoSolv™ was effective in identifying disease without this gender bias.
- EchoSolv™ clearly distinguished between patients with varying severity of disease as well as those at high and low risk of dying.
- 55% of the cases of guideline-defined severe AS cases did not have an active treatment plan.

Future applications of EchoSolv™ – multiple opportunities leveraging NEDA data in structural heart disease

EIQ has flagged several structural heart diseases as potential opportunities to apply EchoSolv™ technology, with mitral regurgitation next in line for new product development based on NEDA data.

Opportunities for growth into other areas of structural heart disease include:

- heart failure
- systolic dysfunction
- diastolic dysfunction
- tricuspid regurgitation.

Commercialisation – Two Stages and Multiple Pathways

The company is pursuing a multi-faceted commercialisation strategy based on rollout of two versions of the platform:

1. **version 1, the 'lite' model of its software platform, which does not require FDA clearance:** aimed at enhancing diagnosis of AS patients that fall within the AHA guidelines.
2. **version 2, the 'pro' version of its software platform, which is subject to FDA clearance:** designed to identify an additional cohort of patients which do not fit into current guidelines but exhibit traits that through application of the software can be stratified according to risk of AS-related mortality.

All of the company's current partnerships to date relate to version 1, given this does not require FDA clearance and is thus ready to commercialise.

Customer value proposition appeals to multiple industry segments and channels

Channel partners to reach end-users

EIQ's attractive value proposition, given the health economics of early diagnosis and risk stratification, paves the way to target multiple industry segments. The company is leveraging three channels and various revenue models to reach healthcare providers and ultimate users of echocardiograms (see Figure 16).

Figure 16: Potential commercialisation pathway across multiple channel partners to reach end-users of echocardiograms

Channel	Potential revenue model	Potential packaging
PACS + reporting	Software as a service – part of an access agreement to a further end-user (e.g., hospital)	Built into device (i.e., integrated into reporting software)
Echocardiography hardware	Licensing agreement	Built into hardware (i.e., into echo trolley/scanning equipment) – fully integrated
Device (valve) manufacturer	Companion sale/co-promoter agreement (typically fixed fee)	Separate software offering

Source: EIQ.

End-user target market: healthcare providers

The ultimate target market for EIQ's product is the users of echocardiograms, the healthcare providers. This includes hospitals, ambulatory surgery centres (ASCs) and cardiologists. The company is focusing on hospitals in the 10–12 key states which account for 80% of all TAVI procedures in the US, as well as on ASCs. It is also targeting cardiologists, who work in hospitals, ASCs and other settings.

Roll-out underway – recent events and strategic partnerships

EIQ has been active on multiple fronts over the past 12 months. The company has accelerated commercial deployment initiatives following the release on 19 April 2023 of positive final results from the clinical trial conducted at St Vincent's Hospitals in Sydney and Melbourne.

HeartX accelerator program – USA

In October 2022, EIQ was selected to participate in the HeartX accelerator program. This program, which helps to fast-track deployment of new cardiovascular innovations, is powered by HealthTech Arkansas and MedAxiom (see below).

Participation in HeartX provides EIQ with the following benefits:

- guaranteed hospital pilot projects and clinical trials within an established network of 7 of the largest healthcare providers in the state. Inclusion in the final cohort was based, in part, on having technologies with the potential to advance cardiovascular innovation and cardiac care at their respective organisations
- an opportunity to accelerate US commercialisation in a collaborative yet cost-effective manner
- additional support for the company's FDA application.

MedAxiom partnership – USA

On 2 May 2023, EIQ entered a strategic partnership with MedAxiom, an American College of Cardiology company. The ACC is the leading professional body for cardiologists in the world's largest cardiology market. MedAxiom is the cardiovascular community's premier source for organisational performance solutions and is linked to over 475 cardiovascular organisations in the US, encompassing 6,500 cardiovascular leaders, over 13,200 clinicians and around 2,700 administrators.

Hydrix Medical – Australia, New Zealand, Singapore

On 2 May 2023, EIQ appointed Melbourne-based Hydrix Medical, a subsidiary of Hydrix Limited (ASX: HYD), as sales partner for Australia (excluding Queensland), New Zealand, and Singapore (subject to regulatory approval).

The initial term of the agreement is 3 years, renewable annually thereafter by mutual consent. It gives Hydrix Medical exclusive rights to promote, market and sell EchoSolv™ products to cardiologists in the agreed territories. Under the agreement, Hydrix will receive a sales commission per customer contract facilitated, paid partly upfront and then annually over the life of the contract.

Cassling: exclusive sales agent/distributor – Midwest region, USA

On 8 May 2023, EIQ appointed Omaha (Nebraska)–based Cassling as its exclusive sales agent in the Midwest region of the USA. Terms of the agreement were not disclosed. Cassling, established in 1984, is a leading provider of imaging and therapeutic technology, services and solutions to the US healthcare market. Under the agreement, Cassling will present EchoSolv™ solution to hospitals, ambulatory surgery centres, and specialty care and outpatient centres in Midwestern states, including Iowa, Missouri, Kansas and others, as well as Texas and Arkansas.

First commercial agreement – Australia

On 8 May 2023, EIQ announced its first commercial deployment of EchoSolv™ in Australia to a private cardiology practice under a SaaS agreement (details undisclosed).

Direct sales channel established for cardiology sector – Queensland, Australia

EIQ has engaged an experienced cardiac sales executive to develop current opportunities for deployment of the EchoSolv™ solution in Queensland in conjunction with the team at Hydrix Medical. The company retains the ability to sell directly in Queensland to ensure EIQ continues to benefit from direct industry engagement and to incorporate market insights into its product roadmap.

Financials

EIQ's history as a med-tech pure play is relatively short.

In October 2021, EIQ (then Houston We Have [HWH.AX]) commenced a strategic realignment of its then three software business segments (med-tech, health insurance analytics, and defence sector services[7]) to focus on the development and application of artificial intelligence for the diagnosis of structural heart diseases following the acquisition of Alert Echo IQ Pty Ltd in May 2021.

This resulted in the rebranding of the company as Echo IQ (EIQ.AX) and, later, the divestment of wholly owned subsidiary Prometheus Information Pty Ltd (a provider of professional services and software to the health insurance sector) in March 2022.

Our key forecasts

Revenue forecasts: Our near-term forecasts largely reflect revenues expected from the commercialisation of EchoSolv™ in the US. Notwithstanding the multiple commercial pathways outlined on page 15, for the purpose of modelling given the early stage of commercialisation of EchoSolv™, we have assumed the company will initially deploy EchoSolv™ using a SaaS model, similar to its first contract win in Australia, and target cardiology-focused ASCs in the US which we estimate at ~11,000.

Expenses: The bulk of EIQ's expenses consist of share-based payment expenses for directors and consultants, followed by employee costs and consulting/professional fees.

EBITDA: Based on our modelling of revenues and expenses, we see EIQ achieving breakeven at the EBITDA line in FY25.

Tax: We estimate that the accumulated losses on the balance sheet at 30 June 2022 totalling $27.7m will offset income tax payable over the medium term. We forecast that tax losses will expire in 2026.

Most recent financial results – variable expenses add flexibility

1HFY23 results represent the most recent and detailed reporting of EIQ's financials. EIQ's expenses contain a high degree of variable costs, most notably consulting and professional fees, which comprise (1) advisory companies (regulatory, etc.), and (2) individual providers of specialist services (medical advisory, etc.).

Figure 17: EIQ 1HFY23 profit and loss

Revenue	37
Government grant and other income	31
Audit fees	(32)
Consulting and professional fees	(760)
Employee costs	(1,099)
Directors' fees	(158)
Total Operating Expenditure	**(2,049)**
EBITDA	**(1,980)**
EBITDA Growth	
D&A expenses	(305)
Total EBIT	**(2,285)**
Finance expenses	0
Other expenses	(250)
Share based payments expenses – directors' and consultants' fees	(2,000)
Share registry and listing fees	(78)
Profit (loss) before tax	**(4,614)**
Income tax	0
Profit (loss) before tax	**(4,614)**
Profit/ loss from discontinued operations	410
Net loss for the year	**(4,203)**

Source: EIQ.

[7] Related to Intelfuze decision making software originally developed by a Commonwealth Research Centre in conjunction with the Australian Defence Force for use in military intelligence and strategy.

Valuation

We value EIQ at A$354m, which equates to A$0.77 per share, or A$0.59 per share (fully diluted) using DCF methodology. This represents a significant premium to current share price of $0.16.

Key assumptions

Regulatory:

- FDA clearance obtained for version 2, the 'pro' version of EchoSolv™, by the end of CY23

Commercialisation:

- US roll-out targeting cardiology-owned ambulatory surgical centres (ASCs)
- ~11,000 cardiology-focused ASCs – estimated based on
  - assumption of 3 cardiologists per ASC
  - 33,662 cardiologists in the US (source: KFF)
- SaaS pricing model of US$5,000 per month in the US
- SaaS pricing model of A$5,000 per month in Australia (given first contract win)

Other key points:

- AUD/USD of 0.7
- Beta of 1.25
- Discount rate of 12.5%
- Shares on issue of 457.7m (source: FactSet)
- Options on issue of 145m

Figure 18: Base-case DCF valuation and key metrics (A$)

		Jun-23	Jun-24	Jun-25	Jun-26	Jun-27	Jun-28	Jun-29	Jun-30	Jun-31	Jun-32	Jun-33
		2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
EBIT	A$m	(3.8)	(1.0)	10.4	34.4	53.6	82.4	82.3	82.3	82.2	82.1	82.0
Tax at standard rate	A$m		0%	0%	0%	30%	30%	30%	30%	30%	30%	30%
Post-tax EBIT	A$m	**(3.8)**	**(1.0)**	**10.4**	**34.4**	**37.5**	**57.7**	**57.6**	**57.6**	**57.5**	**57.5**	**57.4**
Depreciation & Amortization	A$m	(0.4)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.2)	(0.2)	(0.2)
Post-tax cash flow	A$m	**(4.2)**	**(1.4)**	**10.1**	**34.1**	**37.2**	**57.4**	**57.4**	**57.3**	**57.3**	**57.3**	**57.2**
Less capex	A$m	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Less change in working capital	A$m	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Free cash flow	A$m	**(4.1)**	**(1.3)**	**10.2**	**34.2**	**37.3**	**57.5**	**57.4**	**57.4**	**57.4**	**57.3**	**57.3**
Discount coefficient	years		1.1	2.1	3.1	4.1	5.1	6.1	7.1	8.1	9.1	10.1
Discounted cash flow	A$m		**(1.2)**	**8.0**	**23.7**	**23.0**	**31.5**	**28.0**	**24.9**	**22.1**	**19.6**	**17.4**

Sum of discount streams	A$m	197.0	**CAPM**		
Terminal growth	%	1.0%	Risk free rate	%	5.0%
Future value into perpetuity	A$m	503.3	Equity beta	x	1.25
NPV of terminal value	A$m	154.6	Equity risk premium	%	6.0%
PV of cash flows	A$m	351.6	Cost of equity	%	12.5%
PLUS: Value of investments	A$m	-	Debt	%	0%
LESS: Net debt	A$m	(2.6)	Equity	%	100%
Equity value	**A$m**	**354.3**	Interest rate	%	0.0%
Ordinary shares	m	457.7	Tax rate	%	30%
Value per share	**A$**	**0.77**	WACC	%	12.5%

Source: MST Access.

Upside and downside risks to our valuation

- Upside risks to our valuation, based on key drivers, include higher-than-expected penetration of the serviceable market given greater-than-expected contracts won; better-than-assumed pricing for either device and/or SaaS subscriptions; and lower-than-expected operating expenses relating to integration costs and marketing.
- Downside risks to our valuation relate to the same assumptions and include slower-than-expected adoption and higher marketing costs required as a result.

Risks

Commercialisation

Integration and adoption: Adoption of new technology in the medical sector is still a slow process, in part because clinicians tend to resist integrating new approaches into established clinical practice and operating systems. EIQ has designed a comprehensive implementation package containing several options to support rapid integration of EchoSolv™ into existing clinical systems. These options cater to both ongoing monitoring of studies (providing DICOM-compliant tools and REST API) and more infrequent studies such as clinical audits (facilitating direct upload of measurements in CSV format into a secure web application or upload of Study SR files to a secure location).

Hospital sales cycles: Typically, the sales cycles of larger hospitals can be relatively long (12–18 months) which can increase reliance on the distributing partner's ability to target and prioritise appropriate hospitals.

Competition: All technology-based companies face the risk of being overtaken by superior solutions or undercut in price by low-cost competitors. However, direct competition remains limited at this point.

Explosive growth in digital health over recent years has attracted significant levels of early-stage venture capital investment targeting a multitude of applications, including AI software applications in healthcare.

However, the competitive landscape in AI-powered software and med-tech products remains highly fragmented and diverse, in terms of the parts of the value chain that are being targeted.

The most visible application of AI software in healthcare to date has been in the areas of healthcare data integration, reporting functions and patient management administration. These include companies Egnite (primarily focused on using AI to improve patient care through business intelligence and process improvement) and Mpirik (uses AI to improve patient communication and workflow and is designed to reduce the number of patients falling through the follow-up cracks). Active in the imaging space are companies such as US2.ai and Ultromics, but these are not in direct competition to EIQ. Notably, companies targeting guideline products do not have access to the quantum of data available to EIQ (via its agreement with NEDA) to build competing algorithms.

Regulatory

FDA clearance: Version 1 of EchoSolv™ (which identifies patients within AHA guidelines) was launched in December 2022. The company is pursuing FDA clearance of version 2 of EchoSolv™ to identify an additional cohort of patients which, while not fitting into current guidelines, exhibit traits that could be stratified through application of the software by their risk of AS-related mortality.

Reimbursement: Reimbursement is a key driver of adoption by clinicians, contingent on the validation (reader) study and ultimate clearance by the FDA. The company is preparing a FDA 510(k) submission which should benefit from clinical trial support stemming from being selected for the HeartX accelerator program.

Financing

EIQ's first product EchoSolv™ was launched in December 2022. Growing the business in the near term is dependent on cash from revenue which is currently generated solely by EchoSolv™. As such, and until the product is generating sufficient income, the company will be reliant on access to external funding.

Technology

Data confidentiality, integrity and security: The increasing incidence of cyber hacking and data breaches raises concerns over the vulnerability of NEDA to data corruption, which may compromise its value as a primary resource for EIQ's new product development endeavours.

Workflow integration: The ease with which EchoSolv™ can be integrated into existing processes and systems will be an important driver of adoption. However, this will also depend on the client's existing IT infrastructure and level of training required. The company is launching a starter kit to facilitate this process.

Intellectual property

EIQ is using a broad single patent approach across all conditions related to structural heart disease to protect its intellectual property. Its Australian provisional patent application (2022901868) is called 'Systems and Methods for AI-assisted Echocardiography'. Intellectual property risk, notwithstanding the granting of the patent, could be offset by gaining a first-mover advantage, which – given the multifaceted commercialisation activity to date and lack of direct competition in imaging – seems within reach.

Board of Directors, Management Team, and Scientific Advisory Board

Board of Directors

Andrew Grover, Executive Chairman: Mr Grover, Chair of EIQ since its inception, has 25 years' experience as a founder and investor in numerous companies and in growing successful businesses across a diverse range of industries. His businesses have been featured in the BRW Fast 100 and Deloitte's Fast 50 over several years.

Steven Formica, Non-Executive Director: Mr Formica brings significant business management and development experience to EIQ, having led a number of privately held business ventures across multiple industry sectors. He is the non-executive chairman of Ragnar Metals (ASX:RAG) and an investor in a number of ASX-listed entities. He has previously been a director of Jade Gas Holdings (ASX:JGH; formerly High Grade Metals [ASX:HGM]), Orminex (ASX:ONX) and Lindian Resources (ASX:LIN).

Stephen Picton, Non-Executive Director: Mr Picton is an experienced director and business leader. As CEO of mobile virtual network operator goTalk, he increased revenues to >$100m. Mr Picton holds a Bachelor of Science in technology and a Master of Science (Business) from London Business School. He is a Chartered Engineer, a Member of The Institute of Company Directors, and a Sloan Fellow, which was awarded to him in 1993 by the Sloan Foundation as part of the joint MIT, Stanford and LBS program.

Management Team

Philip Woolff, Chief Operating Officer: Mr Woolff leads EIQ's communications and corporate functions. He has worked in a number of market-leading private and publicly listed corporates, holding roles in technology services, premium consumer goods and telecoms. Mr Woolff has lived and worked in North America, Europe, Africa and Australasia, and holds an MBA from a leading Canadian university.

Deon Strydom, Chief Commercial Officer: Mr Strydom is a pharma and med-tech executive with over 17 years' industry experience in commercialisation, M&A, partnerships and marketing. He has held senior roles, both public and private, across key markets including the US, EU, and Asia Pacific with a focus on building and scaling commercialisation efforts. Mr Strydom holds a BA in marketing and an MBA.

Seán Bryceland, Chief Technology Officer: Mr Bryceland is a technology and product leader with experience in strategic innovation, cyber and risk management, and digital transformation. At EIQ he is responsible for integrating cutting-edge technology solutions into healthcare delivery systems, particularly in cardiology. Mr Bryceland has previously led digital and cyber transformation as a government CIO and headed up delivery and R&D for an international life insurance software firm. He holds an honours degree in Information Technology and is currently working toward an MBA at the University of New South Wales.

Professor David Playford, Chief Medical Officer: Prof Playford is Professor and Head of Cardiology Teaching and Research at the University of Notre Dame, Fremantle, Australia. He is a consultant clinical cardiologist at Advara Heart Care, specialising in cardiac imaging, cardiovascular risk and breathlessness assessment. He regularly speaks at national and international conferences and has written a number of highly cited publications. He is founder, director and Chief Investigator of NEDA.

Don Fowler, President USA: Mr Fowler is a senior strategic operating executive and healthcare industry veteran with large-scale budget and P&L experience in the high-technology medical systems sector. Leveraging extensive experience at Siemens Healthcare and Toshiba America Medical Systems, he has served in Chief Executive and Board roles.

Professor Geoff Strange, Chief Strategy & Research Officer: Prof Strange is a health researcher with a specialist interest in applying 'big data' to further our understanding of a variety of cardiovascular diseases. He is Professor at the School of Medicine at the Universities of Sydney and Notre Dame, Australia. He is the Senior Academic Lead for the burden of disease study (cardiovascular heart disease) based at the Heart Research Institute Sydney and is a member of the cardiology research team at Royal Prince Alfred Hospital, Sydney. Prof Strange is Creator, Director and Chief Investigator of NEDA.

Dane Brescacin, VP Regulatory Affairs: Mr Brescacin is responsible for developing and implementing regulatory and quality strategies to obtain market access for EIQ's products. He has 17 years' med-tech experience in both industry and global contract research organisations, working with start-ups and large medical device companies. He has contributed to projects from early product design and development, clinical research and medical writing to successful commercialisation in the US, Europe and Australia.

Jessamyn Lyons, Company Secretary: Ms Lyons is a Chartered Secretary and Fellow of the Governance Institute of Australia. She holds a Bachelor of Commerce from the University of Western Australia with majors in Investment Finance, Corporate Finance and Marketing. She is an experienced Company Secretary, having held roles with Macquarie Bank, UBS (London) and Patersons Securities.

Scientific Advisory Board

Professor Huon H. Gray, CBE MD FRCP FESC MACC: Prof Gray was consultant adult and interventional cardiologist at Southampton University Hospital from 1989 to 2020. In 2003 he was appointed President of the British Cardiac Society, receiving its Mackenzie Medal in 2014. He is honorary professor at Queen Mary University, London and has published widely on various aspects of cardiology and health service delivery. Prof Gray has served in various capacities within the American College of Cardiology (ACC), including as chair of its International Council, on its Board of Trustees, and as a member and then chair of its Governance Committee.

Dr Partho Sengupta, MD MBBS FACC FASE: Dr Sengupta is the Henry Rutgers Professor and the Chief of Division of Cardiology at Rutgers Robert Wood Johnson Medical School & University Hospital. He completed his clinical residency and cardiology fellowship at Mayo Clinic Rochester and Arizona respectively. He has over 250 peer-reviewed publications. Dr Sengupta is an Associate Editor for the *Journal of American College of Cardiology: Imaging* and has served as a member of the Board of Directors for the American Society of Echocardiography (ASE) and as Chair of the ASE Telehealth and New Technology Taskforce. He has won several excellence awards and received ASE's 14th Feigenbaum Lectureship, recognising his major contributions to research in the field of echocardiography.

Dr James D. Thomas, MD FACC FASE FESC: Dr Thomas is a cardiologist at Northwestern Medicine with a clinical focus in valvular heart disease and echocardiography and extensive research into applying physical principles and advanced technology in cardiovascular imaging. He serves as Director for the Center for Heart Valve Disease and Academic Affairs in the Bluhm Cardiovascular Institute and co-directs the Center for Artificial Intelligence in Cardiovascular Disease while serving as Professor of Medicine at Northwestern University's Feinberg School of Medicine. Dr Thomas co-chairs a committee to standardise the measurement of myocardial strain by echocardiography, and serves as lead scientist for ultrasound with NASA, focusing on the effects of space on cardiovascular function. He has over 650 peer-reviewed publications with an h-index of 149.

Dr David Ouyang, MD FACC FAS: Dr Ouyang is a Los Angeles–based cardiologist affiliated with the internationally recognised Cedars-Sinai Medical Center. He is Board Certified in Cardiovascular Disease and Internal Medicine. He has a degree in statistics and completed post-doctoral studies in Computer Science and Biomedical Data Science, and has a particular interest in the application of data to personalise care and improve diagnosis and treatment of cardiovascular disease. Dr Ouyang was awarded the 2018 Merck Research Fellowship at the American College of Cardiology Foundation and received the Edwin Alderman Award for Excellence in Clinical Research in 2020. He has produced many research publications that address deep learning and computer vision of cardiovascular imaging.

Dr Hashim Khan, MD FACC: Dr Khan is a practicing interventional cardiologist at the renowned San Diego Cardiac Center in San Diego, California. He is a Clinical Scholar and engages in cardiovascular research at the Scripps Translational Science Institute. He is board certified in Cardiovascular Diseases, Interventional Cardiology, Echocardiography, Nuclear Cardiology and Internal Medicine.

Dr Jordan Strom, MD MSC FACC FASE: Dr Strom is Associate Director of the Echocardiography Laboratory and Director of Echocardiographic Research at Beth Israel Deaconess Medical Center, Section Head of Cardiovascular Imaging Research at the Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology, and Assistant Professor of Medicine at Harvard Medical School. Dr Strom's research involves evaluation of the relationship of cardiac structure and function to health outcomes, particularly for valvular heart disease, and focuses on the optimal use and timing of cardiac imaging in practice. He has published more than 60 peer-reviewed publications.

Madeline Jankowski, BS ACS RDCS FASE: Ms Jankowski is an advanced cardiac sonographer and echocardiography research associate at Northwestern University. In clinical practice, she focuses on complex valve disease for research trials, hemodynamic stress echocardiography, and advanced imaging tools such as global longitudinal strain imaging and 3D echocardiography. Her research focuses on advanced echocardiography tools and integration of AI into echocardiography.

Dr Michael Mack, MD MACC: Dr Mack is a cardiothoracic surgeon, and is board certified in Internal Medicine, General Surgery, and Thoracic Surgery. He is the Director of the Cardiovascular Service Line for Baylor Scott & White Health, Chair of the Baylor Scott & White Cardiovascular Governance Council and Past President of the Baylor Scott & White Research Institute. Dr Mack was President of the Society of Thoracic Surgeons (STS) 2011 and is Past President of the Thoracic Surgery Foundation for Research and Education (TSFRE) 2009-2011, the Southern Thoracic Surgical Association (STSA) 2009 and the International Society for Minimally Invasive Cardiothoracic Surgery (ISMICS) 2000. He is a Master of the ACC and is an honorary member of the German Society for Thoracic and Cardiovascular Surgery and the Indian Association of Cardiovascular and Thoracic Surgery, Mexican Society of Cardiac Surgery and has received the Presidential Citation of the American College of Cardiology and the Transcatheter Cardiovascular Therapeutics (TCT) Lifetime Achievement Award.

Appendixes

Appendix 1 – Treating aortic stenosis: Transcatheter Aortic Valve Replacement (TAVR)

Valve replacement is the only treatment option with a good prognosis in patients with symptomatic severe AS. However, due to surgical risk associated with patient frailty, comorbidities, age, and severe left ventricular dysfunction, about one-third of the patients over the age of 75 are not referred for surgery. Transcatheter aortic valve replacement (TAVR) is an alternative, less invasive treatment for severe AS.

Patient selection

TAVR, a new and innovative approach to replace a narrowed aortic valve that fails to open properly, is an alternative for individuals:

- at low, intermediate or high risk of complications from surgical aortic valve replacement
- unable to undergo open-heart surgery due to advanced age or presence of cardiovascular risk factors
- with other comorbid conditions
- with a prior history of stroke, chest radiation, open heart surgery, COPD, frailty, renal insufficiency, advanced age and other conditions.

Risks

TAVR has been found to be safe and effective. However, the procedure still carries some risk.

- Valve leaks: Sometimes blood leaks around the new valve because the replacement is not big enough, did not fully expand, or has interference from calcium build-up.
- Pacemakers: When valves open during placement, they can sometimes press on the heart's electrical system and make a pacemaker necessary.
- Kidney damage: The contrast dye used for imaging can damage kidneys, but the problem is usually reversible.
- Vessel damage: Passing catheters through arteries can sometimes damage them. The damage is usually repairable through a catheter or with open vascular surgery.
- Stroke: A small percentage of people undergoing TAVR can develop a stroke, either during the procedure or in the days immediately following it.

Appendix 2 – Aortic stenosis guidelines

Figure 19: Stages of AS

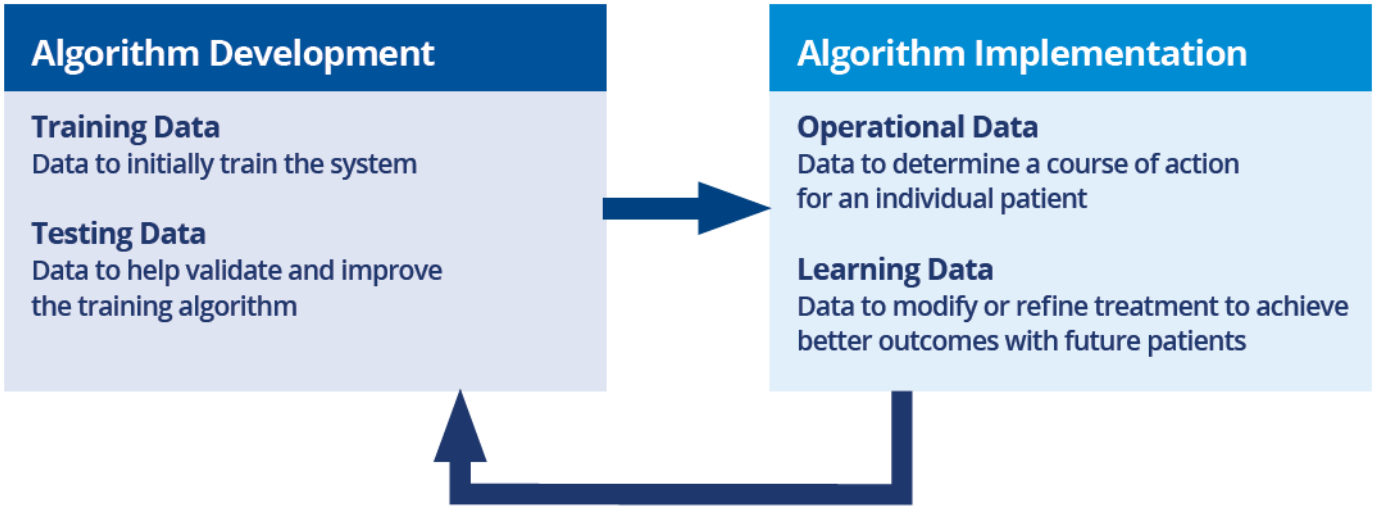
Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk of AS	BAV (or other congenital valve anomaly) Aortic valve sclerosis	Aortic V_{max} <2 m/s with normal leaflet motion	None	None
B	Progressive AS	Mild to moderate leaflet calcification/fibrosis of a bicuspid or trileaflet valve with some reduction in systolic motion or Rheumatic valve changes with commissural fusion	Mild AS: aortic V_{max} 2.0–2.9 m/s or mean ΔP <20 mm Hg Moderate AS: aortic V_{max} 3.0–3.9 m/s or mean ΔP 20–39 mm Hg	Early LV diastolic dysfunction may be present Normal LVEF	None
C: Asymptomatic severe AS					
C1	Asymptomatic severe AS	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg AVA typically is ≤1.0 cm^2 (or AVAi 0.6 cm^2/m^2) but not required to define severe AS Very severe AS is an aortic V_{max} ≥5 m/s or mean P ≥60 mm Hg	LV diastolic dysfunction Mild LV hypertrophy Normal LVEF	None Exercise testing is reasonable to confirm symptom status
C2	Asymptomatic severe AS with LV systolic dysfunction	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg AVA typically ≤1.0 cm^2 (or AVAi 0.6 cm^2/m^2) but not required to define severe AS	LVEF <50%	None
D: Symptomatic severe AS					
D1	Symptomatic severe high-gradient AS	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but may be larger with mixed AS/AR	LV diastolic dysfunction LV hypertrophy Pulmonary hypertension may be present	Exertional dyspnea, decreased exercise tolerance, or HF Exertional angina Exertional syncope or presyncope
D2	Symptomatic severe low-flow, low-gradient AS with reduced LVEF	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	AVA ≤1.0 cm^2 with resting aortic V_{max} <4 m/s or mean ΔP <40 mm Hg Dobutamine stress echocardiography shows AVA <1.0 cm^2 with V_{max} ≥4 m/s at any flow rate	LV diastolic dysfunction LV hypertrophy LVEF <50%	HF Angina Syncope or presyncope
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	AVA ≤1.0 cm^2 (indexed AVA ≤0.6 cm^2/m^2) with an aortic V_{max} <4 m/s or mean ΔP <40 mm Hg AND Stroke volume index <35 mL/m^2 Measured when patient is normotensive (systolic blood pressure <140 mm Hg)	Increased LV relative wall thickness Small LV chamber with low stroke volume Restrictive diastolic filling LVEF ≥50%	HF Angina Syncope or presyncope

AR indicates aortic regurgitation; AS, aortic stenosis; AVA, aortic valve area circulation; AVAi, AVA indexed to body surface area; BAV, bicuspid aortic valve; ΔP, pressure gradient between the LV and aorta HF, heart failure; LV, left ventricular; LVEF, left ventricular ejection fraction; and V_{max}, maximum velocity.

Source: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000923#d1e4306.

Appendix 3 – Using data to build, test and validate machine learning tools

Figure 20: Algorithm development and implementation



Source: Evaluating AI-Enabled Clinical Decision and Diagnostic Support Tools Using Real-World Data: healthpolicy.duke.edu.

Appendix 4 – FDA-cleared AI/ML–enabled devices in cardiology

Figure 21: Artificial intelligence and machine learning (AI/ML)–enabled medical devices (2008–present)

Date of Final Decision	Device	Company
07/27/2022	DeepRhythmAI	Medicalgorithmics S.A.
07/19/2022	Study Watch with Irregular Pulse Monitor (Home), Study Watch with Irregular Pulse Monitor	Verily Life Sciences LLC
07/19/2022	ZEUS System (Zio Watch)	iRhythm Technologies, Inc.
06/29/2022	Eko Murmur Analysis Software (EMAS)	Eko Devices, Inc.
06/03/2022	Atrial Fibrillation History Feature	Apple Inc.
05/31/2022	eMurmur Heart AI	CSD Labs GmbH
04/26/2022	AliveCor QT Service	AliveCor, Inc.
04/01/2022	DEEPVESSEL FFR	KeyaMed NA Inc.
11/03/2021	IM007	Implicity, Inc.
10/22/2021	IRNF App	Apple Inc.
09/08/2021	Feops HEARTguide	Feops NV
06/11/2021	LINQ II Insertable Cardiac Monitor, Zelda AI ECG Classification System	Medtronic, Inc.
05/21/2021	Zio ECG Utilization Software (ZEUS) System	iRhythm Technologies, Inc.
04/01/2021	Gili Pro Biosensor (Also Known as Gili Biosensor System)	Continuse Biometrics Ltd.
03/26/2021	Oxehealth Vital Signs	Oxehealth Limited
03/01/2021	Analytic for Hemodynamic Instability (AHI)	Fifth Eye Inc.
01/09/2021	CLEWICU System (ClewICUserver and ClewICUnitor)	Clew Medical Ltd.
01/08/2021	HeartFlow Analysis	HeartFlow, Inc.
10/09/2020	Stethee Pro 1, Stethee Pro Software System	M3DICINE Pty Ltd.
09/16/2020	VX1	Volta Medical
09/02/2020	RX-1 Rhythm Express Remote Cardiac Monitoring System	VivaQuant Inc.
03/26/2020	Bodyguardian Remote Monitoring System	Preventice Technologies, Inc.
03/20/2020	AI-ECG Tracker	Shenzhen Carewell Electronics Co., Ltd.
01/15/2020	Eko Analysis Software	Eko Devices Inc
12/09/2019	FFRangio	CathWorks Ltd
09/11/2019	PeraMobile and PeraWatch	PeraHealth, Inc.
08/15/2019	Biovitals Analytics Engine	Biofourmis Singapore Pte. Ltd
08/15/2019	HeartfFow FFRct Analysis	HeartFlow, Inc.
07/10/2019	PhysIQ Heart Rhythm and Respiratory Module	PhysIQ, Inc
05/21/2019	Acumen Hypotension Prediction Index - EV1000 Clinical Platform, Acumen Hypotension Prediction Index - Hemosphere Advanced Monitoring Platform, Acumen Hypotension Prediction Index, Hemosphere Advanced Monitoring Platform - Pressure	Edwards Lifeciences, LLC
04/17/2019	EMurmur ID	CSD Labs GmbH
03/29/2019	Loop System	Spry Health, Inc.
03/11/2019	KardiaAI	AliveCor, Inc.
03/07/2019	RhythmAnalytics	Biofourmis Singapore Pte. Ltd.
02/16/2019	Rx-1 Rhythm Express Remote Cardiac Monitoring System	Vivaquant Inc.
01/17/2019	Study Watch	Verily Life Sciences Llc
12/19/2018	FFRangio System	CathWorks Ltd
12/14/2018	Cardio-TriTest v6.5	Cardio-Phoenix Inc.
12/06/2018	FFRct v2.18	HeartFlow, Inc.
11/19/2018	AI-ECG Platform	Shenzhen Carewell Electronics., Ltd.
09/28/2018	FibriCheck	Qompium NV
08/29/2018	Zio AT ECG Monitoring System, Zeus System	IRhythm Technologies, Inc.
05/01/2018	PeraServer and PeraTrend	PeraHealth, Inc.
03/16/2018	Acumen Hypotension Prediction Index (HPI) Feature Software	Edwards Lifesciences LLC
01/04/2018	WAVE Clinical Platform	Excel Medical Electronics, LLC
12/22/2017	SOZO	ImpediMed Limited
11/07/2017	Rooti Rx ECG Event Recorder, Rooti Link APP Software	Rooti Labs Ltd.
09/27/2017	Peerbridge Cor(TM) System	Peerbridge Health Inc.
08/17/2017	SpectralMD DeepView Wound Imaging System 2.0	SpectralMD, Inc.
06/26/2017	CardioLogs ECG Analysis Platform	Cardiologs Technologies
02/23/2017	Reveal LINQ	Medtronic, Inc.
10/19/2016	Tyto Stethoscope	Tyto Care Ltd.
08/24/2016	FFRct v2.0	HeartFlow, Inc.
07/15/2016	Steth IO	Stratoscientific, Inc.
01/13/2016	FFRct	HeartFlow, Inc.
06/11/2015	Personalized Physiology Analytics Engine Software	VGBio, Inc. (DBA PhysIQ)
07/17/2008	Visensia	OBS Medical

Source: https://www.fda.gov/.

Appendix 5 – Share register and options

Figure 22: Top 20 shareholders

Rank	Name	Units	% Units
1	A22 PTY LTD	29,116,414	6.36
2	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	25,000,000	5.46
3	RICHMOND BRIDGE SUPERANNUATION PTY LTD <RICHMOND BRIDGE SUPER A/C>	21,114,854	4.61
4	ALERTE DIGITAL HEALTH PTE LTD	20,636,363	4.51
5	STEVSAND INVESTMENTS PTY LTD <STEVEN FORMICA FAMILY A/C>	17,000,000	3.71
6	BELLCOO INVESTMENTS PTY LTD <THE NORTHLAKE S/F A/C>	12,833,099	2.80
7	ARREDO PTY LTD	11,000,000	2.40
8	SHAH NOMINEES PTY LTD	10,060,162	2.20
9	HUNT PROSPERITY PTY LTD <INVESTIUS PB MICRO CAP A/C>	10,000,000	2.18
10	MR BRIAN JOSEPH GLYNN	8,800,000	1.92
11	XERYUS INTERNATIONAL PTY LTD	6,590,481	1.44
12	MIKADO CORPORATION PTY LTD <JFC SUPERANNUATION A/C>	6,000,000	1.31
13	MR GREGORY PETER WILSON	5,800,000	1.27
14	SHRIVER NOMINEES PTY LTD	5,650,000	1.23
15	MS LAURA BAILEY	5,500,000	1.20
16	KLI PTY LTD <THE T TEH'S FAMILY A/C>	5,340,000	1.17
17	LAKE SPRINGS PTY LTD <THE LAKE SPRINGS S/F A/C>	5,250,000	1.15
18	KING CORPORATE PTY LTD	5,050,000	1.10
19	SHAH NOMINEES PTY LTD <LOUIS CARSTEN SUPER FUND A/C>	5,000,000	1.09
20	GRATITUDE AND UNCONDITIONAL FORGIVENESS PTY LTD	4,960,000	1.08
Totals: Top 20 holders of ORDINARY FULLY PAID SHARES (Total)		**220,701,373**	**48.22**
Total Remaining Holders Balance		**237,003,003**	**51.78**

Source: EIQ.

Figure 23: Unquoted equity securities (30 June 2022)

Class	Total Number of Securities	Total Number of Holders	Number of Holders of 20% or more	Name	Number of Securities
Options Exp 30/6/23 @ $0.12	500,000	1	2	Mr Philip Woolff	500,000
Options Exp 30/6/23 @ $0.20	1,000,000	1	2	Mr Andrew Watts	1,000,000
Options Exp 30/6/24 @ $0.30	1,000,000	1	2	Mr Andrew Watts	1,000,000
Options Exp 09/06/24 @ $0.10	8,000,000	2	2	Colin Street Investments Pty Ltd	3,000,000
				Nest Egg Capital Pty Ltd <Shiva A/C>	5,000,000
Options Exp 09/06/24 @ $0.17	8,000,000	2	2	Colin Street Investments Pty Ltd	3,000,000
				Nest Egg Capital Pty Ltd <Shiva A/C>	5,000,000
Options Exp 09/06/24 @ $0.25	14,000,000	4	2	Colin Street Investments Pty Ltd	5,000,000
				Nest Egg Capital Pty Ltd <Shiva A/C>	7,000,000
Options Exp 09/06/24 @ $0.30	13,000,000	3	2	Colin Street Investments Pty Ltd	5,000,000
				Nest Egg Capital Pty Ltd <Shiva A/C>	7,000,000
Options Exp 17/12/24 @ $0.25	25,000,000	2	2	A22 Pty Limited	15,000,000
				Formica Investments Pty Ltd <Formica Family Super Fund>	10,000,000
Options Exp 02/02/25 @ $0.25	16,000,000	13	1	Mr Deon Strydom <Deon Strydom Family A/C>	5,000,000
Options Exp 31/05/24 @ $0.05	47,500,000	9	2	Bellcoo Investments Pty Ltd <The Northlake S/F A/C>	10,000,000
				Shah Nominees Pty Ltd <Louis Carsten Super Fund A/C>	13,000,000
Options Exp 29/10/24 @ $ 0.25	2,000,000	1	1	Richmond Bridge Superannuation Pty Ltd <Richmond Bridge Super A	2,000,000
Options Exp 01/11/24 @ $0.04	1,000,000	1	1	Mr George Preston	1,000,000

Source: EIQ.

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