



ASX ANNOUNCEMENT

31 July 2024

## Cardiex June 2024 Quarter Update

### Highlights:

- Robust Q4 and record FY24 financial results.
- Expanded product capabilities to drive continued revenue growth with strong internal projections for FY25 and beyond.
- Initial CONNEQT Pulse units have arrived in the USA and Australia and are being distributed to strategic healthcare partners for pilot programs, including extensive user testing and evaluation.
- Pre-launch activities for Pulse have exceeded expectations leading to an increase in the first full production run from 3,000 to 8,000 units (Q1 FY25).
- Multiple new regulatory clearances being sought in new geographic markets.
- Targeted marketing initiatives for the Pulse are accelerating to build awareness and drive leads through key industry events, online marketing, and other digital and social channels.
- Strengthened financial position with funding commitments from C2 Ventures.
- Investor webinar details and closing CEO comments.

Dear Fellow Shareholders,

On behalf of the Company I'm pleased to present our final Quarterly Update for FY 2024.

As we approach a pivotal moment in our journey, I'm thrilled to highlight our recent achievements and the exciting developments on the horizon. Our dedicated efforts across various sectors have led to impressive financial results and a growing interest in our innovative products. With a strong foundation in place, including significant advancements in our ATCOR division and successful product launches, we are well placed for continued success.

In the lead-up to the launch of the CONNEQT Pulse, we are now preparing to shift our focus towards a more targeted and strategic marketing approach. This will include leveraging a diverse array of industry, social, and digital channels to amplify our reach and drive both awareness and sales. With new partnerships, expanded product capabilities, and continuing strategic initiatives, we are confidently moving forward to meet the increasing demand and deliver transformative solutions to our market.

### **1. ATCOR Update**

The ATCOR division achieved impressive financial results for both the period and the full financial year, with the Group reporting total unaudited revenue and other income of \$12.4m - a substantial increase from \$6.0m for FY23. This marks a record revenue year for the Company and highlights our ongoing success in expanding our market presence and diversifying our product offerings.

We expect this upward trend to continue as we prepare to introduce innovative solutions tailored to ATCOR's core clinical, pharmaceutical, and healthcare markets.

This quarter, our pharmaceutical business unit has been actively involved in various initiatives, including participating in major industry conferences such as DIA 2024. These events are crucial for expanding our pipeline of clinical trial prospects. Additionally, we have launched multiple demand

generation campaigns targeting both existing and new clients. A standout in these campaigns has been Cardiex's Pulse, which now enables us to offer a comprehensive suite of products for conducting assessments across multiple modalities, including in-office visits, 24-hour ambulatory monitoring, and in-home assessments for all phases of clinical development.

These efforts have generated significant interest in hemodynamic studies with applications in heart failure, metabolic health (including Type 2 Diabetes and weight management), as well as neurology, ophthalmology, and inflammatory diseases. This growing interest has resulted in a robust pipeline and opportunities exceeding \$5 million for deploying devices and services in large-scale clinical trials in the near future.

We anticipate this upward trend to continue as we prepare to introduce innovative solutions tailored to ATCOR's core clinical and healthcare markets.

## ***2. CONNEQT Product Update***

### ***(a) Update on the CONNEQT Pulse***

In a significant milestone, the initial shipments of the CONNEQT Pulse arrived in the USA and Australia in July. These shipments included critical Over-the-Air (OTA) firmware upgrades, which are essential for improving the functionality, security, and user experience of the Pulse.

Currently, our Quality Assurance Team is conducting rigorous system-level testing. This involves systematically and repeatedly evaluating the entire data path—from the readings captured by the Pulse device to their correct display in the mobile application and subsequent upload to the CONNEQT Cloud.

We are also placing a strong focus on testing the interaction between patients and physicians, as well as reviewing the educational content provided with the CONNEQT app. This ensures a seamless end-user experience and helps users fully understand and effectively utilize the device. By addressing these aspects, we aim to enhance the overall satisfaction and performance of the Pulse in real-world scenarios.

### ***(b) Pulse Pilot Programs and Strategic Partnerships***

Pulse units are currently being distributed company-wide for extensive user testing and evaluation. Additionally, we have begun supplying several units to select "pilot" clinical partners, including key opinion leaders (KOLs) and esteemed members of our clinician network. These units have been strategically allocated to a diverse group of external users across various market segments, allowing us to collect a broad spectrum of perspectives and invaluable feedback. This feedback is crucial for refining and enhancing the product to better meet the needs of our varied user base. By collaborating with these influential individuals, we aim to gain insights that will guide our ongoing development and ensure we effectively address the specific requirements of different market segments.

### ***PhysioAge***

We have been actively forging strategic partnerships to expand the integration of the Pulse into broader health solutions. Our first collaboration is with PhysioAge, where we are integrating the Pulse into their health analytics platform. This partnership focuses on the concierge and functional medicine markets, enhancing PhysioAge's capability to deliver comprehensive health assessments by incorporating advanced arterial health metrics.

By including the Pulse, PhysioAge can offer users deeper insights into their cardiovascular health and overall wellness. This integration will also enable more precise monitoring and personalized health recommendations based on the detailed data captured by the Pulse.

PhysioAge founder, Dr. Joe Raffaele, MD, has already commenced initial marketing efforts in relation to the Pulse on his social channels.

#### *Heartbeat Health*

Additionally, our partnership with Heartbeat Health, a nationwide network of cardiologists, will enable the prescription of the Pulse to consumers. This collaboration aims to make advanced arterial health monitoring more accessible by allowing consumers to purchase the Pulse easily online. This will provide an upgraded and comprehensive health monitoring solution that surpasses traditional blood pressure measurements.

By offering the Pulse through our e-commerce platform ([conneqthealth.com](https://conneqthealth.com)) we are ensuring that consumers have convenient access to advanced health monitoring tools, facilitating better health management and proactive care.

#### ***(c) Pulse Sales & Operations***

In our June Sales and Operations Update (ASX June 17, 2024), we reported that the first full production run of 3,000 units is on track for delivery in Q1 FY25. Pre-launch activities are gaining momentum, and at the current rate, we anticipate over 20,000 people will be on the waitlist for the Pulse by the time we begin accepting orders.

In response to the high demand and strong clinical interest, we have increased the first production run to 8,000 units and will continue to ramp up deliveries throughout the calendar year. To support this expansion, we have also boosted our chip inventory to over 50,000 units, ensuring we can meet future demand. Our current production facilities are equipped to produce up to 5,000 chips per month.

#### ***(d) CONNEQT Wearable Technology Development***

We have made significant strides in developing our wearable technology, the CONNEQT Band. The first phase of the clinical validation study for the Band has commenced in collaboration with Macquarie University's Blood Pressure and Arterial Function (BPAF) Laboratory. This study aims to validate the Band's performance by comparing it to Cardiex's industry-standard XCEL device in preparation of our upcoming regulatory submission for FDA clearance.

#### ***(e) Regulatory Update***

##### *Regulatory Update on the CONNEQT Pulse*

We are actively working to extend the Pulse's existing RX (prescription) 510(k) FDA clearance to include "over the counter" (OTC) sales. This extension will allow us to sell the Pulse directly to consumers without requiring a prescription.

Once OTC clearance is achieved, we will continue to maintain our partnership with Heartbeat Health as this collaboration offers valuable clinical and telehealth services, and other valuable economic opportunities through their extensive cardiologist network.

Having successfully completed our usability study—the primary requirement for OTC submission—we are on track to file for this additional clearance in Q2 FY25.

### *Australia, New Zealand, and Additional Regulatory Geographies.*

Beyond the USA, we are using our FDA clearance as a springboard to expand into Australia and New Zealand. We are on track to submit applications to the TGA and Medsafe in Q2 FY25.

Our next objective is to secure CE and UKCA marks for Europe and the UK. Obtaining these approvals will pave the way for market entry across Asia and EMEA, as global demand for the Pulse continues to grow.

### *Regulatory Update on the CONNEQT Band*

The pre-submission process for an FDA 510(k) clearance of the Band has already commenced with our full submission targeted in Q1 FY25.

### *Regulatory Update on the SphygmoCor XCEL*

We are actively expanding into new markets with our SphygmoCor XCEL device. Efforts are underway in India, Singapore, Thailand, Vietnam, and Indonesia, with submissions and registrations planned for these regions throughout FY25.

## ***(f) Research and Patent Update***

### *Research Publications Highlighting Our Wearable Technology*

A forthcoming paper authored by academics from Macquarie University, also including Dr. Ahmad Qasem, our Chief Science and Research Officer, is set to be featured in the August edition of *PULSE: The International Journal on Comprehensive Care and Prevention of Vascular Diseases*. The study highlights significant scientific findings related to Cardiex's wearable technology, specifically its use of a finger PPG sensor to capture crucial arterial biomarkers.

### *Award of New Wearable Patent*

This month, Cardiex proudly announced the official publication of a key wearable patent by the United States Patent and Trademark Office (USPTO) (Patent #US12,029,5380). This patent solidifies our leadership in wearable technology by protecting our advanced method for converting photoplethysmography (PPG) signals into high-fidelity central aortic pressure waveforms. These waveforms are essential as they capture various cardiovascular features and biomarkers, providing deeper insights into heart health and cardiovascular conditions. This achievement highlights Cardiex's commitment to developing cutting-edge solutions in cardiovascular health and underscores the potential for improved patient outcomes through more accurate and reliable monitoring technologies.

## ***3. Group Sales and Marketing Initiatives.***

Our sales and marketing initiatives continue to accelerate as we focus on expanding the sales channels for our existing products, as well as positioning ourselves for the launch of the Pulse.

Our key focus has been on building awareness and leads through industry events, online marketing, and other digital initiatives; including for the quarter:

1. The relaunch of Cardiex.com with easier navigation and a focus on driving newsletter and product sales leads (noting that we have already experienced a 67% increase in user traffic and a 184% increase in page views since this effort);
2. The relaunch of ConneqtHealth.com with a focus on generating a waitlist and email marketing list for pre-orders;

3. Retiring our AtcorMedical.com website as we look to consolidate our branding and product sales through the Cardiex brand;
4. Cardiex sponsorship of leading industry websites including JAMA (*Journal of the American Medical Association*), JACC (*Journal of the American College of Cardiology*) and Hypertension;
5. An increase in our online ads, programmatic advertising, and search engine marketing;
6. Launch of our “waitlist” program for the Pulse (with over 20,000 people anticipated to be on the waitlist for the Pulse by the time we begin accepting orders (based on our current run-rate));
7. Launch of our “Nurture Campaign” for the Pulse - a targeted, weekly, email campaign to “waitlist” subscribers whereby we build momentum and knowledge around the Pulse and its features in advance of pre-orders;
8. Launch of our “Cardiex Insights” email campaign focusing on our traditional research and clinical markets;
9. A successful American Heart Association Webinar on Vascular Age which was moderated by our Chief Strategy Officer, Catherine Liao;
10. Preparations to launch expanded social, influencer, video, and “key opinion leader” (KOL) campaigns in advance of the launch of the Pulse;
11. The conclusion of our Arterial Research Initiative Contest, which attracted research proposals from around the world (all incorporating our devices as the lead research tool) and over 20,000 votes; and
12. Multiple industry events including ACSM (*American College of Sports Medicine*), NAA (*North American Artery*), and DIA (*Drug Information Association*) - where we showcased our new branding, offered complimentary arterial assessments, and generated 260 qualified sales leads.

#### **4. Corporate Update**

##### **(a) Cash and Expenditure**

Total unaudited revenue and other income for the year through the end of quarter is \$12.4m.

During the quarter, revenue in traditional medical markets was \$870k, and cash receipts from customers was \$886k. The Company had a cash balance of \$481k as at 30 June 2024 (not including the Funding Commitment Agreement with C2 Ventures (C2V) that provides for an additional \$6m, which increases cash reserves to \$6.5m).

During the quarter, Cardiex spent \$459k on product development and operating costs on new and existing products, a decrease of \$1.1m on the prior quarter expenditure of \$1.5m. Research and development expenditure totalled \$386k.

Administration and corporate costs totalled \$695k for the quarter, a decrease of \$162k on the prior quarter expenditure of \$857k.

During the quarter, Cardiex received an FY23 R&D Tax Incentive of \$692k, which was used to repay its existing R&D loan facility with Mitchell Asset Management (“MAM”).

Net cash used in operating activities for the quarter totalled \$2.8m, a decrease of \$3.3m on the prior quarter, due to the pay down of historical creditors in the prior quarter.

Closing cash for the quarter was \$481k, with a further \$6m to be received before the end of 2024 from C2 Ventures as part of the Funding Commitment Agreement - providing \$6.5m of available funding which is believed to be sufficient to fund the Company's growth initiatives, its operations, and to meet its business objectives.

Payments to related parties and their associates in the quarter were \$150k and all related to remuneration for services under existing services agreements.

***(b) Extraordinary General Meeting of Shareholders - 3 June 2024***

On 3 June 2024, the Company held an Extraordinary General Meeting (EGM), seeking shareholder approval for the issue of shares and options to C2V under the terms of the Funding Commitment Agreement to enable the remaining \$6 million to be invested by C2V - and on receipt by the Company, be immediately converted into shares and options. In addition, regarding the non-executive directors (King Nelson and the recently appointed Charlie Taylor) we were seeking shareholder approval for Mr Taylor's appointment, and the issue of share options to both non-executive directors.

All resolutions at the EGM were passed, including the two C2V resolutions, which enabled Cardix to fully complete the \$14 million fundraising package announced in late 2023.

***(c) Post Quarter Investment Webinar.***

The Company will be holding a post-quarter investor webinar on Tuesday, 6 August 2024 (AEST) / Monday, 5 August 2024 (PDT).

The webinar will be hosted by Cardix's CEO Craig Cooper who will be joined by Niall Cairns (Executive Chairman), Catherine Liao (Chief Strategy Officer), Mark Gorelick (Chief Product Officer), Brian Schaechter (Senior Director of Sales - Pharmaceutical), and Rosemarie Diehl (Senior Director of Demand Generation), who will be providing an update on the Company's business, product, sales, and operating activities for the last quarter.

**Webinar details:**

**Date:** Tuesday, 6 August 2024 (AEST) / Monday, 5 August 2024 (PDT).

**Time:** 9:00am (AEST)/ 4:00pm (PDT).

**Registration:** [https://us06web.zoom.us/webinar/register/WN\\_lYgDGu-vSXKr5rydWEvAEQ](https://us06web.zoom.us/webinar/register/WN_lYgDGu-vSXKr5rydWEvAEQ)

**Dial in Details:** After registering, you will receive a confirmation email containing information about joining the webinar.

## **5. Final Comments.**

As we near the launch of the CONNEQT Pulse, we are excited to share our strong progress and showcase our continuing execution on our product vision. Our impressive financial results and record revenue for the ATCOR division highlights our successful market expansion, sales growth, and opportunity for product diversification. With a robust waitlist for the Pulse and innovative developments in our wearable technology, we are well-positioned to continue on our upward trajectory.

Looking ahead, our marketing efforts will increasingly focus on targeted channels to drive both awareness and sales. And with new partnerships, ongoing product development, and a clear path to market expansion, we are confident in our ability to meet the growing demand and deliver exceptional value through our cutting-edge healthcare technologies.



Craig Cooper

Chief Executive Officer

**Approved by the Board of Directors and Released by the Company Secretary**

**- ENDS -**

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## **About Cardiex**

Cardiex develops technologies to enable humans to lead better, more productive, and longer lives. The Company's suite of products includes medical and home health devices and digital solutions for hypertension, cardiovascular disease, and other vascular health disorders - all based on the Company's market leading SphygmoCor® vascular biomarker technology. Cardiex is listed on the Australian Stock Exchange ("ASX:CDX").