



ASX ANNOUNCEMENT

31 October 2024

## Cardiex September 2024 Quarter Update

### Highlights:

- Manufacturing of the initial 8,000 CONNEQT Pulse units commenced with the expected arrival of units in the USA late-November/early December.
- Pulse waitlist now exceeds 20,000 with activities now focused on sales conversion.
- Completed clinical validation study of wearable technology, with an FDA pre-submission meeting scheduled for November to advance the clearance process.
- Completion of usability study for submission for additional OTC clearance for the Pulse.
- Strong clinical sales pipeline with momentum towards new Q2 contracts.
- Grand prize winner of the U.S. National Institute of Health's RADx® Maternal Health Challenge securing US\$525,000 in prize funding.
- New R&D Term Loan Facility with Mitchell Asset Management to provide additional flexibility with R&D initiatives and working capital requirements.

Dear Fellow Shareholders,

On behalf of the Company, I'm pleased to present our Quarterly Update for September 2024 (Q1 FY25). This quarter, our primary focus has been preparing for the launch of the Pulse and expanding our sales pipeline for the Clinical Trials Group. While our revenue for the quarter was in line with the prior quarter, we remain optimistic about our growth projections for the full year 2025. With pre-sales for the Pulse starting in November and key clinical trial contracts in the process of being secured, we are confident in our ability to achieve our targets moving forward.

### **1. Clinical Trials Group Update**

Our Clinical Trials Group continues to build a strong revenue pipeline for 2025.

As we move through the first quarter of our fiscal year, we have continued to build on the momentum discussed in our July webinar. Our strategic engagement with key partners across the pharmaceutical, biotechnology, and clinical trial sectors continues to progress. For example, discussions with a global CRO regarding multiple trials relating to GLP1's in both type 2 diabetes and obesity in over 30 countries are advancing through procurement stages. Similarly, another discussion focusing on cardiovascular safety for a neurological therapy, is transitioning to Phase III clinical trials as well as multiple new compounds proceeding to Phase I programs, with our services set to replace those of a previous vendor.

We are also broadening our reach into new therapeutic areas. Notably, we are expanding our work with an existing customer from nephrology into their respiratory and cardiac franchise teams, opening multiple new revenue streams. Additionally, we are in talks with a major player in the Psoriasis market looking at the possibilities of cardiac benefits from their current biological therapy that is in the market. These developments underscore the strong partnerships we have built through consistent follow-ups and operational reliability.

Our commitment to product versatility, especially in devices designed for home, office, and ambulatory assessments, continues to drive our robust pharmaceutical pipeline, **currently valued at approximately US \$8 million**. While some trials await sponsor approvals, the ongoing discussions are very encouraging. Delays are typical in the industry, often influenced by regulatory approvals and sponsor decisions. Nevertheless, we are well-positioned to achieve our goals, secure new contracts in the coming quarters, and importantly, meet our revenue projections for 2025.

## **2. CONNEQT Product Update**

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

**In a significant milestone for the Company, manufacturing has now commenced on our initial order of 8,000 CONNEQT Pulse units.** We have been advised by our manufacturing partner, that these units are now expected to arrive in the USA and be available for distribution late-November/early December.

In July, we shared that the waitlist for CONNEQT Pulse had just under 7,000 sign-ups. Today, we are pleased to announce that **we have now surpassed our target of 20,000 sign-ups**. This growth underscores the rising consumer demand for our arterial health assessment service and reflects the success of our marketing efforts.

We have seen strong engagement among our waitlist with our six-part nurturing campaign, designed to educate them on the benefits of monitoring arterial health. This nurturing campaign has been critical in ensuring that potential customers fully understand the value of the CONNEQT Pulse, helping to ease their concerns about price and solidifying their commitment to pre-order. By maintaining regular communication, we have been able to build trust and keep our audience engaged throughout the lead-up to launch.

Another key milestone has been reached this week, as **we have now commenced extending exclusive invitations to our waitlist to enable them to place pre-orders**. This phased rollout is being undertaken so that we may ensure a smooth customer experience and efficiently manage the conversion of waitlist sign-ups into orders, sales and product deliveries. Initial responses have been positive, and we expect continued momentum as we roll out additional waves in the coming weeks.

Following our pre-order program, we plan to launch a comprehensive marketing, sales, influencer, KOL (Key Opinion Leader), and digital strategy with a strong presence at the start of the New Year. This timing aligns with the "New Year, New You" retail surge, a period when health and wellness products traditionally experience a substantial boost in sales.

Reaching these milestones reaffirms the strength of our strategy and positions us for sustained growth. As we scale, we expect this demand to support revenue generation and accelerate our market entry in both consumer and clinical sectors. We are excited about the road ahead and will continue to keep you updated on our progress.

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

During the quarter, we completed the first phase of the clinical validation study for the CONNEQT Band in partnership with Macquarie University's Blood Pressure and Arterial Function (BPAF) Laboratory. This collaborative study focused on validating the Band's performance through a direct comparison with Cardiex's industry-standard XCEL device. Achieving alignment with XCEL's well-established metrics was a key objective, aimed at ensuring the Band's capability to deliver clinical-grade accuracy. The success of this phase provides the foundation for our next steps and underscores the Band's potential to set a new standard in wearable arterial health monitoring.

With the successful completion of this initial phase, we are advancing to the next stage of regulatory requirements. The positive outcomes from the validation study offer a robust basis as we prepare our FDA submission, a critical step toward obtaining clearance for the CONNEQT Band. Our team is diligently compiling the necessary documentation and data to meet the stringent regulatory benchmarks expected of a medical-grade device, underscoring our commitment to aligning with FDA standards.

***(d) RADx® Grant Funding***

Post quarter end, the Company was pleased to be selected as one of five grand prize winners in the final phase of the National Institutes of Health's (NIH) Rapid Acceleration of Diagnostics (RADx®) Tech for Maternal Health Challenge (the Challenge).

The Company had previously passed the 'Initial Assessment' and 'Interim Milestone' phases of the Challenge and had secured a total of US\$415,000 in cash grants. The Company was then selected to participate in the final phase of the Challenge, and after being announced as one of five winners, has secured a further US\$525,000 in cash grant funding.

***(e) Regulatory Update***

*(i) Regulatory Update on the CONNEQT Pulse*

We are actively working to expand the Pulse's existing RX (prescription) 510(k) FDA clearance to include "over the counter" (OTC) sales, which would allow us to offer the Pulse directly to consumers without requiring a prescription.

A key step in this process involved completing a human factors study in the second half of FY24 to assess usability and ensure that the Pulse's design supports effective, independent use by consumers. As an essential requirement for OTC clearance, this study enabled us to evaluate and refine the user experience, validating the device's intuitiveness and safety for use outside a clinical setting.

With the study now complete and results finalized, we are moving into the final stages of our OTC submission preparation, remaining 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.

*(ii) Regulatory Update on the CONNEQT Band*

In further support of the wearable development efforts described above, we have scheduled a pre-submission meeting with the FDA in November. This meeting is a proactive step, allowing us to present our findings, address any questions, and refine our submission approach with FDA feedback to ensure expeditious processing and clearance. Through this engagement, we aim to streamline the clearance process and ensure a clear path forward for bringing the CONNEQT Band to market.

Our strategy is to introduce a groundbreaking, FDA-cleared set of wearable parameters uniquely designed for both clinical and consumer use. Currently, no wearable device has been recommended by leading cardiovascular associations for clinical practice—as other wearable devices also require a

calibrated pressure measurement using a cuff. The CONNEQT parameters overcome this limitation by eliminating the additional need for calibration with a cuff, offering a significant value proposition for global healthcare providers and wearable tech companies in search of medical-grade solutions.

### **3. Sales & Marketing Update.**

In Q1, we prioritized strengthening our sales and marketing infrastructure to enhance efficiency and visibility throughout our lead-to-close process. A key focus was on expanding our Salesforce database and refining the tools and workflows for lead management, forecasting, and quoting. These upgrades provide a deeper understanding of the customer journey and sales cycle, enabling our teams to better identify and close high-potential enterprise deals. The insights gained from these enhancements are expected to streamline our processes, bolster customer engagement, and ultimately boost revenue.

Additionally, we continued refining our programmatic ad campaigns, crafting targeted messaging to resonate more powerfully with our clinical and pharma audiences. This involved ongoing testing and optimization to ensure relevance and engagement within these key segments. We also advanced preparations for upcoming Q2 events, securing participation and developing promotional materials for high-profile industry gatherings such as Artery, Medica, AHA (American Heart Association), and A4M (American Academy of Anti-Aging Medicine). These events present valuable opportunities to showcase our products, connect with influential stakeholders, and reinforce our brand within the clinical and pharmaceutical sectors.

### **4. Corporate Update**

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

During the quarter, revenue in traditional medical markets was \$0.8m, and cash receipts from customers was \$0.5m. The Company had cash reserves of \$4.30m on 30 September 2024, consisting of cash balances of \$0.55m and \$3.75m that remains to be drawn down under the Funding Commitment Agreement with C2 Ventures (C2V).

During the quarter, Cardiex spent \$0.15m on product development and operating costs on new and existing products, a decrease of \$0.3m on the prior quarter expenditure of \$0.45m. R&D expenditure totalled \$0.5m, an increase of \$0.1m on the prior quarter's expenditure of \$0.4m.

Administration and corporate costs totalled \$0.8m for the quarter, an increase of \$0.1m on the prior quarter expenditure of \$0.7m.

Net cash used in operating activities for the quarter totalled \$3.1m, an increase of \$0.3m on the prior quarter.

Closing cash for the quarter was \$0.55m, which will be bolstered by the remaining \$3.75m available under the C2V Funding Commitment Agreement (\$2.25m was drawn during the quarter) thus providing Cardiex with total cash reserves of \$4.30m.

Payments to related parties and their associates in the quarter were \$0.07m and all related to remuneration for services under existing services agreements.

#### **(b) R&D Term Loan Facility**

During the quarter, Cardiex entered into a new R&D Term Loan Facility of \$1.12m with Mitchell Asset Management Pty Ltd ("MAM"), which was advanced as a prepayment of forecast Research and Development Tax Incentives that are anticipated to be receipted by the Company for the 30 June 2024 and 30 June 2025 financial years. The facility attracts interest at 18% per annum. \$0.6m of

the principal is due upon receipt of the 2024 R&D Tax Incentive Refund (with an extended due date of 30 November 2024), with the balance secured by the 2025 R&D Tax Incentive Refund due by 31 October 2025.

Also, during the quarter, Cardiex received approval from AusIndustry for the inclusion of overseas software development costs in its R&D Tax Incentive claims for FY2024-FY2026. Cardiex is now anticipating a total refund of \$1.4 million in Q2, a significant increase from prior year claims. Once received, funds will be used towards repayment of the R&D Term Loan Facility and Working Capital Facility held with MAM.

### **Final Comments**

While our revenue for the quarter was in line with the previous quarter, we are strongly optimistic about our growth projections for FY25. These are supported by the upcoming pre-sales for the Pulse and its full rollout, along with our pipeline for new clinical trials revenue that is anticipated to commence in Q2.

Moving forward, we are focused on growing sustainable revenues in the high growth markets we are targeting in order to underwrite the success and shareholder value that we have all been working towards.

Reaching this stage has not been without its challenges, as introducing a new technology to market is never an easy path. Now, as we transition from development to sales and marketing, we are finally in a position to realize the full value of these efforts and I want to extend my thanks to all our shareholders for their support throughout this journey.



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").