

ASX ANNOUNCEMENT 24 April 2024

## **Cardiex March 2024 Quarter Update**

## Highlights:

- On track for record annual company revenues (>\$11m).
- Inventory/production update and marketing activities ahead of commercial launch of the Pulse biometric monitor.
- CONNEQT Pulse accepted for inclusion in the American Medical Association's Validated Device Listing (VDL), affirming its clinical accuracy and reliability.
- Successful completion of HEARTsense Wearable Study validating SphygmoCor® biomarker technology in wearables.
- New patent awarded by USPTO for wearable PPG sensor technology.
- Completion of Institutional Placement.
- Completion of Entitlement Offer partially underwritten by C2 Ventures (C2V).
- Increase in the Funding Commitment Agreement (FCA) with C2V due to partial underwriting of the Entitlement Offer.
- Cash and committed funding (under FCA) > \$10m to fund growth initiatives, operations and achievement of business objectives.
- Appointment of new non-executive Director.
- Extraordinary General Meeting on or shortly after 24 May to approve the FCA.
- Relisting of shares on ASX.
- Post quarter investor webinar scheduled for 24 April.
- CEO Final Comments.

## Cardiex Limited (ASX:CDX, Cardiex, the Company) March 2024 Quarter Update.

On behalf of management and the Board, I am pleased to provide shareholders with an update on recent activities.

As we move towards the end of fiscal year 2024 we also move closer towards a number of significant and material milestones for the Company. Headlining this update is record Company revenue and other income of over \$11m underpinned by continuing strong

performance in our Clinical Trial Services Group - a revenue trend we expect to continue into FY 2025.

Importantly, with our recent funding round, and further financial support from C2 Ventures, we are firmly focused on executing against a successful launch of our new products and solutions which are slated for the year - including:

- 1. the Pulse biometric monitor (Q1 FY 2025);
- 2. our "CONNEQT Patient Management Platform" a SaaS based tablet monitoring solution for clinicians to utilize for remote patient monitoring (Q1 FY 2025);
- our "Decentralized Trial Management Platform" a SaaS based monitoring solution developed for pharmaceutical companies and clinical research organizations to use in clinical trials for remotely managing clinical trials (Q1 FY 2025);
- 4. the CONNEQT app to support consumers and patients in their health journey;
- 5. the launch of the conneqthealth.com eCommerce platform (Q4 FY 2024) to allow both "pre-orders" and direct to patient sales of the Pulse online;
- 6. the relaunch of cardiex.com (Q4 FY 2024);
- 7. the launch of a Nationwide cardiology telehealth network fully integrated with the conneqthealth.com eCommerce platform (Q4 FY 2024); and
- 8. a full marketing, education, distribution, and sales program to support the above.

In addition, we are in pre-submission planning on two further FDA clearances to enable us to expand on the above and to support the FY 2025 revenue and sales targets of the Company (see "CEO Final Comments" below). These include additional FDA clearances for:

- 1. OTC ("over the counter") to enable sales direct through traditional retail channels; and
- the CONNEQT wearable band technology.

Both of these submissions are currently being slated for Q1 FY 2025.

Further updates are as follows:

#### 1. ATCOR Update.

The ATCOR division continued to deliver strong financial performance for the period with total revenues for the financial year up to the end of the March quarter of

\$10,042,906 compared to \$4,604,284 for the full FY 2023. This represents a record revenue year for the Company.

We expect this strong growth to continue as we move towards launching a suite of new products that provide unique solutions focused on ATCOR's traditional clinical and healthcare markets.

## 2. CONNEQT Product Update

## (a) Update on CONNEQT Pulse.

Currently we are expecting our first shipments of the Pulse to arrive in the USA and Australia in mid-May. We had previously advised that these initial shipments would arrive in March with delays resulting from additional Over-the-Air (OTA) firmware upgrades that were required. OTA updates are crucial in enhancing the functionality, security, and user experience of the Pulse. Enabling timely updates as we scale is essential for the success of our Pulse launch and for continued engagement with our customers. These shipments are our initial production run to allow us to continue with pre-sale marketing to our key clinical, pharmaceutical, and industry partnerships. At that time we will also be escalating our pre-sales activities through our websites and direct marketing and other online channels. Our first full production run will then follow shortly thereafter to allow us to start delivering products to market in Q1 FY 2025. Our current Pulse pre-sales pipeline on minimal marketing efforts to date stands at approximately US\$500K. Importantly, we also have 40,370 Pulse chips in inventory plus additional pending orders.

During the quarter, we continued to implement strategies to actively market the Pulse through various industry channels and association events. Business development initiatives targeted the entire healthcare spectrum, spanning traditional cardiology practices through to the research and risk management industries. Additionally, efforts were directed at industry standards bodies like A4M (American Academy of Anti-Aging Medicine) and the American Heart Association (AHA) to integrate our SphygmoCor biometric technology into AHA educational and training curriculum for managing cardiovascular disease.

Our immediate sales efforts are concentrated on pivotal traditional markets, involving both existing and prospective clinician, pharmaceutical, and research partners capable of seamlessly integrating our new devices into clinical settings. As highlighted in my 'Letter to Shareholders' on 9 October, the Company is actively pursuing multiple partnerships in specific therapeutic areas. Current opportunities encompass heart

failure and cardiology, Alzheimer's and cognitive health, cash pay and concierge physicians, and pregnancy and maternal health. A modest breakthrough in market share within any of these segments individually signifies a substantial opportunity for the Company.

These efforts are significantly supported by the acceptance of the Pulse for inclusion in the *American Medical Association's (AMA) Validated Device Listing* (VDL), a recognition that affirms its clinical accuracy and reliability. This endorsement enhances the trust and credibility of our product among healthcare professionals, further positioning us as leaders in the market for innovative, clinically validated health technologies. We are currently awaiting the final administrative steps from the AMA before its official listing in the VDL.

The longer-term strategy involves integrating our products and solutions across multiple new healthcare sectors, particularly those reliant on healthcare risk management. With our technology's ability to identify risk at an earlier stage for various health disorders, we anticipate significant value and cost-savings across the wider healthcare ecosystem.

In an effort to foster efficient sales growth, a demand generation leader has been brought onto the team to overhaul marketing and demand-generation, delivering an integrated sales system with a unified dashboard for prospecting and upselling. With these systems now established, we have launched a number of multi-channel customer outreach campaigns through email, webinars, and events. This includes an expanded events schedule leading up to the Pulse launch and showcasing the CONNEQT Band technology to a broader audience including:

- ACSM (American College of Sports Medicine), 5/28-5/31/2024 Boston, MA;
- NAA (North American Artery Conference), 6/14-15/2024 Aurora, Colorado;
- DIA (Drug Industry Association), 6/16-20 San Diego, California;
- AHA (American Heart Association), 11/16-18 Chicago, IL;
- Artery24, 10/10-11/2024 Cardiff, Wales;
- Medica 11/11-14/2024 Düsseldorf, Germany; and
- A4M Longevity Fest (American Academy of Anti-Aging Medicine), 12/13-14/2024
   Las Vegas, NV

Please contact us if you are attending any of these events and would like to meet or see a demonstration.

## (b) CONNEQT Wearable Technology Development

We have made significant progress in the development of our CONNEQT wearable technology after completing the initial validation of the technology in October 2024.

Our current activities are focused on FDA pre-submission requirements in anticipation of formal submission being made for clearance early in Q1 FY 2025 - including the following recent milestones:

## Successful completion of HEARTsense Wearable Study

Post quarter, we successfully completed our primary study validating the use of our SphygmoCor® biomarker technology in wearables by way of a PPG (Photoplethysmogram) sensor (the "HEARTsense Study"). The objective of the HEARTsense Study was to successfully demonstrate the ability to extract vascular biomarkers from a wearable PPG sensor that could previously only be achieved with the Company's "gold standard" XCEL biometric monitor, and the soon to be released Pulse biometric monitor.

The HEARTsense Study showed that the same proprietary XCEL technology can now be ported into a wearable device in a format compatible with commonly used wearable sensor devices.

Completion of the HEARTsense Study is a key step for us as we prepare to lodge our FDA submission for clearance of the CONNEQT Band wearable technology in Q1 FY 2025, as well as being an important step towards commercialization.

Results of the HEARTsense Study have been submitted for publication in a leading peer-reviewed medical and scientific journal.

# United States Patents and Trademarks Office (USPTO) awards new patent for wearable PPG sensor technology

Post quarter, we were advised we had been awarded another patent (US 2021/0369129 A1) for our CONNEQT Band wearable technology. The CONNEQT Band technology patent employs a unique PPG sensor enabling the precise capture of key biometric indicators of disease not available on any current wearable health device.

The CONNEQT Band technology patent overcomes the limitations of traditional health monitoring methods with a novel sensor placed on the side of wearables to capture arterial signals from the fingertips.

Importantly, Cardiex now holds exclusive rights to market, sell or license its wearable health technology in a number of device formats, enabling us to both launch our own devices and to forge partnerships and license our technology to other leading brands looking to deploy FDA-cleared medical grade health solutions.

The new patent for the CONNEQT Band adds to an existing portfolio of patents that demonstrate the Company's expertise and leadership in wearable technology.

## 3. Corporate Update

## (a) Cash and Expenditure

Total revenue and other income for the year through the end of quarter is \$11.2m.

During the quarter, revenue in traditional medical markets was \$0.6m, and cash receipts from customers was \$0.7m. The Company had a cash balance of \$4.1m as at 31 March 2024 (not including the Funding Commitment Agreement with C2 Ventures that provides for an additional \$6m, which increases cash reserves to \$10.1m - see further below).

During the quarter, Cardiex spent \$1.54m on product development and operating costs on new and existing products, an increase of \$1.05m on the prior quarter expenditure of \$0.49m. Research and development expenditure totalled \$576k.

Administration and corporate costs totalled \$0.86m for the quarter, a decrease of \$0.35m on the prior quarter expenditure of \$1.21m.

Net cash used in operating activities for the quarter totalled \$6.11m, of which \$2.75m was used to settle 2023 trade creditor balances (the total reduction in trade creditor balances during the quarter was \$3.7m). The below table reflects the normalized quarterly operating cash flows, after removing the impact of the payment of non-recurring items incurred in prior reporting periods.

	Current quarter \$A'000
Receipts from customers	690
Payments for	
(a) research and development	(199)
(b) product manufacturing and operating costs	(606)
(c) advertising and marketing	(186)
(d) leased assets	(58)
(e) staff costs	(2,650)
(f) administration and corporate costs	(347)
Interest received	1
Net cash from / (used in) operating activities	(3,355)

Closing cash for the quarter was \$4.1m, with a further \$6m to be received before the end of 2024 from C2 Ventures as part of the Funding Commitment Agreement, providing \$10.1m of available funding. This is believed to be sufficient to fund the Company's growth initiatives, its operations, and to meet its business objectives.

Though the expenses of related parties and their associates relating to the current quarter were \$128k, payments to related parties and their associates in the quarter were \$875k, as \$747k relating to prior quarters (1 July 2022 - 31 December 2023) was paid. All payments related to remuneration for services under existing services agreements.

#### (b) Completion of Institutional Placement and Entitlement Offer

During the quarter, the Company completed its non-renounceable pro-rata entitlement offer to raise \$4 million (before costs). Combined with the completion of the \$4 million Institutional Placement, the Company raised a total of \$8 million (before costs).

The Institutional Placement was led by Regal Funds Management and C2 Ventures (C2V), the entity associated with directors Niall Cairns and Craig Cooper, and included other new institutional investors. In addition, the Entitlement Offer was well supported by eligible shareholders and new investors who participated via a Shortfall Offer. The Entitlement Offer was also partially underwritten by C2V. Under the terms of the Underwriting Agreement C2V invested \$934,012.45 representing 23% of the Entitlement Offer. In total C2V invested \$2.5 million of the \$8 million raised (before costs), which is separate and in addition to C2V's additional \$6m financial commitment under the FCA (discussed below).

Subscription proceeds combined with operational receipts from the core business will be applied towards working capital requirements of the business and corporate activities.

## (c) Funding Commitment Agreement Update with C2 Ventures (C2V)

On 14 March, the Company announced an update to the FCA with C2V. The Company and C2V entered into a variation of the FCA announced on 8 November 2023, by increasing the facility limit by \$966,434.40 which brings the total facility limit to \$8,466,434.40 (with \$6 million remaining undrawn).

This variation and increased investment from C2V is primarily the result of C2V's underwriting of the Entitlement Offer and to ensure Cardiex completed the previously announced \$14 million fund-raising package (\$4 million Institutional Placement, \$4 million Entitlement Offer and \$6 million FCA).

Shareholder approval of the updated FCA with C2V will be sought at an upcoming Extraordinary General Meeting of Shareholders outlined below.

## (d) Appointment of Director

Effective 1 March 2024, Mr. Charlie Taylor was appointed an independent non-executive Director of the Company. Mr. Taylor is a recently retired Senior Partner of McKinsey with over 30 years' experience in local and international advisory for both private and public sector healthcare organizations. He joins the Board as an Australian based Director.

Mr. Taylor's current roles include non-executive Director of Healius Limited (ASX: HLS), a part-time senior board advisor at McKinsey for the Health and Public Sector practice, a Director of MacLaughlin River Pastoral Company, a member of the strategic advisory committee For Purpose Investment Partners, and Chair of the NSW Innovation and Productivity Commission.

#### (e) Extraordinary General Meeting of Shareholders - 1 February 2024

On 1 February, 2024 the Company held an Extraordinary General Meeting (EGM), seeking shareholder approval for 13 resolutions relating to the issue of shares and options in the Placement, related party participation in the Placement, issue of options to the 2023 Convertible Note investors (including related party participation) and refreshment of the Company's placement capacity, as per the Notice of Meeting

released on the ASX on 4 January 2024. All Resolutions were passed, which enabled the Placement to be completed and approved C2V's participation.

## (f) Re-Quotation of Shares on ASX

Following the completion of the \$14 million fund-raising package and dialogue with ASX, the Company's securities recommenced trading on ASX on 26 February 2024, lifting the suspension which had been in place since 28 September 2023.

## (g) Proposed Extraordinary General Meeting of Shareholders - on or shortly after 24 May 2024

The Company will be holding an Extraordinary General Meeting (EGM) on or around 24 May 2024, seeking shareholder approval for the issue of shares and options to C2V under the terms of the Funding Commitment Agreement. This will enable the remaining \$6 million to be invested by C2V to, on receipt by the Company, be immediately converted into shares and options. In addition, regarding the non-executive directors (Messrs King Nelson and the recently appointed Charlie Taylor) we are seeking shareholder approval for Mr Taylor's appointment, and the issue of share options to both non-executive directors. Passing of the two C2V resolutions at this meeting enables Cardiex to fully complete the \$14 million fundraising package announced in late 2023.

## (h) Post Quarter Investment Webinar.

Post quarter, the Company will be hosting an investor webinar to provide an update on the Company's business, product, sales, and operating activities.

Joining me on the webinar will be Niall Cairns (Executive Chairman), Catherine Liao (Chief Strategy Officer), Mark Gorelick (Chief Product Officer), and Rosemarie Diehl (Senior Director of Demand Generation).

#### Webinar details:

Date: Wednesday, 24 April 2024 (AEST) / Tuesday, 23 April 2024 (PDT)

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

**Registration:** <a href="https://us06web.zoom.us/webinar/register/WN">https://us06web.zoom.us/webinar/register/WN</a> rtrGqy0EQIqBZBgkm0

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**Dial in** After registering, you will receive a confirmation email containing

**Details:** information about joining the webinar.

**Q&A:** Participants can submit questions in advance to contact@cardiex.com

#### **CEO Final Comments.**

Finally, as we move to close out a record revenue year I am excited about FY25 and the opportunity to build on our FY24 financial success moving forward.

A key driver of our strategy is creating novel use cases in untapped therapeutic areas where we have a technology advantage, and creating "category ownership" in those sectors.

Also, as we move into our planning for the near future we anticipate strong growth in both revenues and shareholder value - a belief that is underpinned by C2 Ventures continued significant financial commitment to the Company and the opportunity we have ahead.

When you look at our last three financial years of total revenue and other income in FY22 (~5.5m), FY23 (~6.0m), and FY24's year to date \$11.2m, I believe our FY25 growth targets are achievable and are strongly supported by our product and sales and marketing plan.

More details on our growth, operational, and sales plans will be presented at the upcoming webinar.

Until then, thank you all for your continuing support and a special thanks to our new and existing shareholders who supported the recent fundraise.

All my best in health,

Craig Cooper - CEO

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

#### - ENDS -

For more information, please contact:

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#### **About Cardiex**

Cardiex's mission is to increase longevity through medical technology advancements in vascular health. 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").