



ASX ANNOUNCEMENT

28 April 2023

CardieX March 2023 Quarter Update

Highlights:

- The US FDA granted 510(k) clearance for the CONNEQT Pulse, a world-first multi-use vascular biometric monitor incorporating SphygmoCor® central blood pressure technology.
- Expansion of clinical trials with key partners and new opportunities in progress, increasing the clinical trial pipeline to US\$20M+ for FY24 and FY25.
- Advancement to the final phase of the NIH Maternal Health Challenge.
- New ATCOR partnership with Power to advance patient-centric clinical trial recruitment diversity.
- Successful \$4.05m Placement completed to support growth initiatives across the business.
- Anticipated lodgement of upcoming notice of Extraordinary General Meeting.

CardieX Limited (ASX:CDX, CardieX, the “Company”) is pleased to provide the following updates on its activities during the March 2023 quarter.

1. CONNEQT Update

Our CONNEQT division continued to gain momentum during the quarter as we focused on the launch of new devices.

CONNEQT Pulse granted 510(k) clearance by FDA

In a major milestone subsequent to period end, the Company announced it has been granted 510(k) clearance from the US Food and Drug Administration (FDA) for the CONNEQT Pulse (Pulse) – a multi-use vascular biometric monitor that provides measurements of both brachial blood pressure (the pressure at your arm) and **central blood** pressure (the pressure at your heart/aorta) along with arterial waveform analysis and other unique vascular biomarkers not available with traditional blood pressure monitors.



CONNEQT Pulse with mobile app

Pulse is an integral part of a new digital and device ecosystem built upon CardieX's SphygmoCor® central blood pressure technology. Previous FDA cleared devices using CardieX's SphygmoCor® technology have predominantly been used in specialist medical and research settings and in clinical trials that have "fixed" trial sites (where trial participants are required to physically visit the trial clinic to be monitored).

The Pulse is targeted at new, high growth market opportunities and expands the Company's SphygmoCor technology into the home, primary care physician office, and the decentralized clinical trial market (where trial participants can now participate in a trial wherever they are physically located).

Available for prescription to patients who need to monitor their heart health and other vascular diseases, the device offers a user-friendly interface that makes it easy for individuals to track their blood pressures and other vascular biomarkers regularly, empowering them to take more control of their cardiovascular health.

The Pulse will be marketed under the Company's CONNEQT brand and is scheduled to be commercially available in Q3 of this year under the Company's current production plan which has been pursued in parallel to the receipt of anticipated FDA clearance.

Multiple additional FDA clearances are currently being prepared for the Pulse for specific disease states and use cases.



CONNEQT Band Update

The Company continued to progress the development of the CONNEQT Band “cuffless” wearable and during the quarter completed the Design Validation Test (DVT) stage to ensure the device can be mass produced while meeting cosmetic and environmental requirements.

We now have product-ready devices required to begin the electronics certifications stage, prior to pursuing clinical validation and regulatory approval.

NIH Maternal Health Challenge Update

During the quarter, the Company advanced to the final phase of the National Institutes of Health (NIH) RADx Tech for Maternal Health Challenge in the United States.

Having been selected from the Viability Assessment Phase where a US\$20,000 cash prize was received, CardieX has now successfully completed the Deep Dive Assessment Phase, where a detailed review of the scientific/technological, clinical and commercialization potential of the CONNEQT suite of devices and software has been completed.

The Company received an additional cash prize of US\$75,000 for being selected as part of the Phase 2 review.

CardieX is now one of ten companies to progress to the final round of the Challenge, the Technology Assessment Phase, which will see a team of healthcare technology commercialization and content experts assess the Company’s submission, the CONNEQT suite of devices (Pulse and CONNEQT Band) and software, across a defined evaluation criteria including a detailed review of the scientific/technological, clinical, accessibility and usability, regulatory, and commercialization potential of the technology.

Should the Company be successful in all phases of the Challenge, it stands to receive up to US\$895,000 in prize money. More importantly, final selection would provide the Pulse with a defacto endorsement by the NIH in one of the more significant markets the Company is targeting with the device – maternal health.

CONNEQT Pulse at CES 2023

During the quarter, the Company participated in one of the world’s largest technology events, the Consumer Electronics Show (CES), held annually in Las Vegas. The Company used this premier event to unveil the CONNEQT Pulse (Pulse). This event was a resounding success for the Company with Pulse being selected as a ‘CES 2023 Innovation Award Honoree’ by an elite panel of industry expert judges. This year’s CES Innovation Awards program received a record number of over 2,100 submissions.

CES was an important marketing event for the Company. The CONNEQT booth was very well attended throughout the four-day event and strong coverage was secured in leading U.S. trade and industry publications, which will be invaluable as the Company prepares to launch the Pulse, subject to receiving the required regulatory approvals.



Leadership Update

During the quarter, CardieX hired Josh Stevens as President of CONNEQT. Josh will be responsible for developing and executing the go-to-market strategy for the CONNEQT devices and solutions.

Josh is senior healthcare and technology executive with more than 25 years' experience across business and commercial strategy, executive and team development, growth and GTM strategies, M&A, operations, and digital health strategies.

2. ATCOR Update

The ATCOR division continued to make good progress during the quarter with a pipeline of over \$US20 million in active development for FY24 and FY25.

New Partnership with Power

During the quarter, ATCOR announced a new partnership with Power, a fast growing patient recruitment marketplace democratizing access to clinical trials for all patients. The new partnership will allow ATCOR and Power to advance patient-centric recruitment diversity and increase patient access across all clinical trial models (conventional, hybrid and decentralized).

Under the partnership, ATCOR and Power will conduct collaborative research and advance underrepresented patient access to clinical trials and clinical research within Alzheimer's disease, women's health, diabetes, and cardiovascular disease.

The partnership with Power enables an innovative new approach for screening patients with novel inclusion/exclusion criteria to improve both patient diversity and access, with the primary goal of enhancing patient reported outcomes.

3. Corporate

(a) Cash and Expenditure

During the quarter, revenue in traditional medical markets was \$1.3m, and cash receipts from customers was \$799k, a decrease of \$1.6m compared to the prior quarter, primarily due to the receipt of significant deposits for clinical trials in the December quarter. The Company had a cash balance of \$1.28m as at 31 March 2023.

During the quarter, CardieX spent \$749k on product development and operating costs on new and existing products. Research and development expenditure totalled \$778k, a decrease of 35% compared to the prior quarter.

Marketing costs increased to \$307k for the quarter, primarily due to the CONNEQT's participation at the 2023 CES in Las Vegas in January (as noted above).

Payments to related parties and their associates in the quarter were \$289k and all related to remuneration for services under existing services agreements.



(b) Placement

During the quarter, CardieX successfully completed a placement of 13,481,377 new fully paid ordinary shares in the Company raising a total of \$4.05 million, at an issue price of \$0.30 per share with a 1 for 2 free-attaching unlisted option, exercisable at \$0.50, expiring 1 year from the date of issue.

The Placement received corner-stone support from existing Directors which will be in addition the above placement details as it will be subject to shareholder approval at the Company's next annual general meeting.

Funds raised from the placement have and will be used to support new product initiatives and provide additional working capital for existing operations, corporate activities, and regulatory requirements for new product launches.

(c) Upcoming Notice of Extraordinary General Meeting and Potential US Dual Listing

The Company continues to position itself for a potential dual listing on a US exchange and a wider capital raising associated with that listing.

As part of this initiative there is a need for a shareholder meeting to be held in the coming months to enable CardieX to seek approval for the US listing capital raise, as well as refreshing its existing placement capacity under LR7.1 and 7.1A. The Company will provide notice of such a meeting once it has the required regulatory approvals.

On behalf of the Board and senior management I would like to thank all our shareholders and partners for their continuing support.

A handwritten signature in black ink, appearing to read "Craig Cooper".

Craig Cooper

Chief Executive Officer

Approved by the Board of Directors and Released by Jarrod White, Director.

- ENDS -



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About CardieX

CardieX is a health technology company focused on devices & solutions for the world's largest population health disorders. Its ATCOR subsidiary is a world leader in the monitoring of vascular biomarkers for clinical trials and health care research based on the Company's "gold standard" SphygmoCor® central blood pressure technology. CardieX's CONNEQT subsidiary develops and markets medical devices, digital solutions, and wearables for home health, remote patient monitoring, and decentralized clinical trials.