



ASX ANNOUNCEMENT

31 October 2022

CardieX September 2022 Quarter Update

Highlights:

- Ongoing correspondence with the FDA - targeting 510(k) clearance for the Pulse in late 2022.
- Appointment of Toni Hofhine as Vice President of Clinical Operations (ATCOR subsidiary) to take advantage of growth opportunities in the clinical trial services market.
- Successful \$4.33M Placement completed and oversubscribed \$1.593M Share Purchase Plan (SPP) to accelerate key growth initiatives across the business.
- Extension of current R&D and debt funded facility terms to 31 December 2023 underway.
- Directors have committed to invest \$1m (included in the \$4.33m Placement), subject to shareholder approval at the upcoming AGM on 30 November 2022 announced this day.

This communication shall not constitute an offer to sell, or the solicitation of an offer to buy, any securities, nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction, or an applicable exemption from such requirements.

CardieX Limited (ASX:CDX, CardieX, the "Company") provides the following updates on its activities during the September 2022 quarter.

1. CONNEQT Product Development

Pulse Regulatory Approvals

During the quarter, the Company continued to make good progress in relation to regulatory approvals required for the CONNEQT Pulse.

As part of the process, the Company collaborated with the FDA and completed a second round submission of information and anticipates receiving 510(k) clearance for the Pulse in late 2022, in time for our participation and exhibition at the Consumer Electronics Show (CES) in Las Vegas in January, 2023.

Subject to final FDA clearance, Pulse will be the first dual arterial health monitor to incorporate a full suite of patented and trademarked heart and vascular health parameters beyond traditional blood pressure focused on the home health, remote patient monitoring, and decentralized clinical trial markets.

2. CONNEQT Band Update and Establishment of CONNEQT Labs

The Company continues to progress the development of the CONNEQT Band, along with our partners, Fenda and LifeQ and is on track with previously announced milestones for release.



3. ATCOR Update

ATCOR Clinical Trial Contracts

Our clinical trial services market continues to expand and is the focus of our ATCOR business development efforts.

During the quarter, CardieX hired Toni Hofhine as Vice President of Clinical Operations within ATCOR. As the lead clinical trials executive in this group, Toni will be responsible for overall strategy, planning and clinical development. She will also help to expand the operations and new team requirements to execute on the tremendous opportunities we see for our products in the clinical trials market.

Toni is a global senior commercial and operations leader and scientist with more than 30 years' experience across drug discovery through patient delivery. She is passionate about improving human health through collaboration, strategy, and process efficiencies that are at the intersection of clinical research and patient care.

Our current (in negotiation) pipeline for clinical trials is over US\$8m. In October, we signed and commenced the initiation phase of a major new clinical trial contract. This contract, when fully executed, will be the largest in the Company's history, and is expected to be formally signed, commenced and invoiced during the December quarter.

Toni reports to Chris Dax, the President of our ATCOR subsidiary.

Other ATCOR Corporate Activity

Separate to our clinical trial efforts the Company continues to aggressively pursue multiple other business development opportunities for the licensing of its SphygmoCor® technology to third-party medical device companies. We anticipate an announcement regarding the first of these new efforts during the current financial year.

Multiple trade shows and other events are also scheduled for the ATCOR sales team throughout the remainder of the year.

4. Corporate

(a) Cash and Expenditure

During the quarter, revenue in traditional medical markets was \$558k, and cash receipts from customers decreased by 857k to \$665k compared to the prior quarter. The Company had a cash balance of \$2.9m as at 30 September 2022. In addition, director commitments of \$1m in the recent capital raise, which are subject to shareholder approval at the upcoming AGM, are expected to be received in the December quarter. Including this \$1m would have given CardieX cash reserves of \$3.9m as at the end of the quarter.

During the quarter, CardieX spent \$344k on product development and operating costs on new and existing products. Research and development expenditure totalled \$839k, primarily due to ongoing costs involved in developing the CONNEQT Pulse and CONNEQT Band devices.



(b) Placement and SPP

During the Quarter CardieX successfully completed a placement of 14,433,337 new fully paid ordinary shares in the Company raising \$4.33 million (m) at an issue price of \$0.30 per share with a 1 for 3 free attaching unlisted option, exercisable at \$0.45, and expiring one year from the date of issue. Directors committed to invest \$1m in the placement, subject to shareholder approval that is being sought at the upcoming AGM on 30 November 2022.

In addition to the placement, CardieX announced a Share Purchase Plan (SPP) offering existing shareholders an opportunity to apply for up to \$30,000 of new shares in the Company at \$0.30 per share. The Company received applications for fully paid ordinary shares from eligible shareholders under the SPP in the amount of \$1.593m (before costs), representing a 59.3% over-subscription over the originally targeted raise of \$1.0m. The Company elected to accept the full \$1.593m of valid applications.

Funds raised from the Placement and SPP will primarily be used to support and accelerate new product initiatives related to the Company's CONNEQT subsidiary as well as corporate initiatives in the USA.

Payments to related parties and their associates in the quarter were \$240k and all related to remuneration for services under existing services agreements.

(c) Mitchell Asset Management – Facility Update

The Company notes with reference to existing R&D funding/debt facility with Mitchell Asset Management (due to expire 31 October 2022) that it is in the process of documenting binding terms to extend the current drawn down value of ~\$1.265m on the following basis:

- Expiry of facility: 31/12/23
- Interest rate: 16% from 01/11/22
- CardieX's full 2022 R&D tax incentive refund to be applied to the current balance owed and tax return to be lodged no later than 31/01/23
- Any balance after that 2022 R&D refund has been offset can be:
 - Paid out in cash with no interest or fees payable under the current facility terms following the month end of the FY2022 R&D payout; or
 - Secured against the Company's FY23 R&D refund and paid on or before the end of the extended facility term of 31/12/23.

The Company will keep the market apprised and release a note on the execution of binding terms once in place.

(d) USA Listing Update

The Company continues to position itself for a potential dual ASX / NASDAQ or NYSE listing. We and our advisory team have made meaningful progress over the quarter to achieve this key objective, and will continue to keep the market updated with our progress. A major task that is currently underway is upgrading the audit of the Company's financial statements, from IFRS to US PCAOB IFRS, which is on track for completion before Christmas.



5. CEO Comments

CardieX has made strong progress this quarter on all fronts for both our traditional ATCOR business as well as the product development and regulatory approvals for our new suite of CONNEQT products.

In August, the Company launched a \$4.33m Placement and SPP to accelerate our key growth initiatives across the business. As well as attracting strong demand from domestic institutions, family offices, and sophisticated investors in the Placement, the oversubscription of the SPP above the targeted \$1m from shareholders is testament to the confidence in the Company's strong growth plan and vision. This was achieved despite the continued downturn in global financial markets.

In September, we welcomed Toni Hofhine to our ATCOR executive team to lead the expansion of our Clinical Trial Solutions team, which we believe will be a significant revenue generator for the Company going forward – especially with the launch of our Pulse device which provides a full decentralized clinical trial solution for our traditional partners such as Bayer, Novartis, AstraZeneca, GSK, and others. Toni brings more than 30 years of industry experience, and we are excited to have her on the team.

Additionally, we continue to build a strong pipeline for clinical trial contracts which is set to make a substantial contribution to revenues for the group as we move into 2023 with our current pipeline in negotiation at over US\$8m.

A lot of effort is being directed to the launch of the Pulse device which we are showcasing at CES in Las Vegas in January 2023. Our booth looks amazing and we also have some very exciting news to share on November 19 in regards to an industry award we have already received for the Pulse (the award being subject to an embargo by the relevant association subject to their formal announcement).

We continue to receive a high level of inbound interest and excitement about the Pulse launch from industry and global associations including the Hypertension Society, the International Society of Hypertension, and the World Hypertension League to name a few. The common theme being the excitement around having central blood pressure and arterial stiffness parameters available in a cloud connected device that will be available for remote patient monitoring and decentralized clinical trials. We are also actively progressing with "launch" partnerships in maternal and cognitive health, as well as hospital and clinician practices for cardiovascular health.

In addition, in the coming weeks we will be announcing a strategic technology acquisition that adds to our wearable development and R&D. As part of the acquisition two leading wearable technology executives (including the company's co-founder) will be joining our team.

As previously advised, our capital market focus is to achieve the dual listing of the Company on a primary USA exchange, either NASDAQ or NYSE. We and our advisory team have continued to make significant progress over the quarter to achieve this key corporate objective and will continue to update the market on our progress. Due to the US Securities and Exchange Commission (SEC) rules we are unable to comment any further on progress or status of this activity.



As always, on behalf of the Board and all of our team members, thank you for all your 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.

For more information please contact:

Australia:

Investor Relations

Rod Hinchcliffe rod.hinchcliffe@mcpartners.com.au

Media Relations

Melissa Hamilton melissa.hamilton@mcpartners.com.au

USA:

Investor Relations

Mathew Selinger Managing Director Integrous Communications mselinger@integcom.us

About CardieX

CardieX is a global health technology company. Its ATCOR subsidiary is a world leader in medical devices for hypertension, cardiovascular disease, and other vascular health disorders 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, primary clinician, and other healthcare channels. CardieX is listed on the Australian Stock Exchange (ASX:CDX).

Forward Looking Information

This press release contains forward-looking statements. These forward-looking statements are not based on historical fact and include statements regarding: anticipated regulatory approval for the CONNEQT Pulse and related timing; the development of the CONNEQT Band and progression towards previously announced milestones; the Company's pipeline for clinical trials for ATCOR and related contracts and timing; business development opportunities for the licensing of the Company's SphygmoCor technology; anticipated cash receipts; and a potential dual listing of the Company's securities on ASX / NASDAQ or NYSE. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond the Company's control, include, but are not limited to, uncertainties related to regulatory approvals, as well as the other risks identified in the Company's filings with the Australian Stock Exchange. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.