



ASX ANNOUNCEMENT

29 July 2022

CardieX June 2022 Quarter Update

Highlights:

- **Significant progress with regulatory approvals for CONNEQT Pulse Dual Blood Pressure Monitor and companion App:**
 - US FDA 510(k) clearance submitted for CONNEQT Pulse.
 - CONNEQT App classified as a Medical Device Data System (MDDS) by US FDA and ready for launch.
- CONNEQT Pulse product launch schedule on track.
- CONNEQT Band update and announcement of CONNEQT Labs headed by Dr. Ahmad Qasem.
- Announcement of expanded release of the Mobvoi TicWatch GTH Pro to additional major markets.
- Significant growth continues in clinical trial services market – strongest sales pipeline in Company history.
- Corporate development update.
- Participation/Exhibition at CES 2023 announced.
- Total cash reserves of \$1.46 million at 30 June 2022.
- Investor Update Webinar details.
- CEO Comments and USA Listing Update.

On behalf of CardieX Limited (CardieX, the “Company”), I’m pleased to provide the following update on our activities during the June 2022 quarter.

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1. CONNEQT Product Development



Pulse and App Regulatory Approvals

During the quarter, the Company was pleased to report significant progress has been made in relation to regulatory approvals that are required for the CONNEQT Pulse and App.

Towards the end of June, a US FDA 510(k) clearance application for the CONNEQT Pulse Dual Blood Pressure Monitor was submitted in conjunction with manufacturing partner, Andon – a significant milestone for the Company.

Subject to final FDA clearance, Pulse will be the first arterial health monitor to incorporate a full suite of patented and trademarked heart and vascular health parameters beyond traditional blood pressure.

Pulse targets the large and growing home health, remote patient monitoring (RPM) and decentralized clinical trial (DCT) markets, significantly expanding the commercial opportunities for the Company.

Pulse is an integral part of a new digital and device ecosystem for both consumers and clinicians built upon CardieX's existing "gold standard" FDA-cleared SphygmoCor® central blood pressure technology.

Pulse will integrate with the CONNEQT App to provide medical-grade health insights into a unique and world-first suite of arterial health features – enabling consumers and patients to make more informed decisions about their health. Pulse also features cloud-based remote patient monitoring, patient record sharing, and health coaching features.



Advance Praise for The Pulse

"ATCOR's Pulse device has the potential to significantly improve treatment decisions by physicians and the health outcomes of patients through the use of advanced blood pressure and vascular health technologies."

Hunter Champion, MD, PhD
Cardiologist
Southeastern Cardiologists Associates

"ATCOR's "gold standard" blood pressure technology is now being made available to all healthcare providers and clinicians with the company's new Pulse device. The cardiovascular insights and accuracy obtained through ATCOR's SphygmoCor technology are revolutionary, impactful and based on current scientific clinical studies regarding blood pressure and cardiovascular outcomes."

Mark C. Houston MD MS
Director - Saint Thomas Medical Group, Saint Thomas Hospital,
Nashville, Tennessee

"The Pulse enables healthcare practitioners to obtain unique cardiovascular health insights in order to inform better decision making around treatment. Importantly, **the Pulse is also the first device to target widespread adoption of arterial stiffness and central blood pressure as key indicators of cardiovascular health.**"

John R. Cockcroft
Dept Advanced Cardiology,
Columbia University Medical Centre,
New York

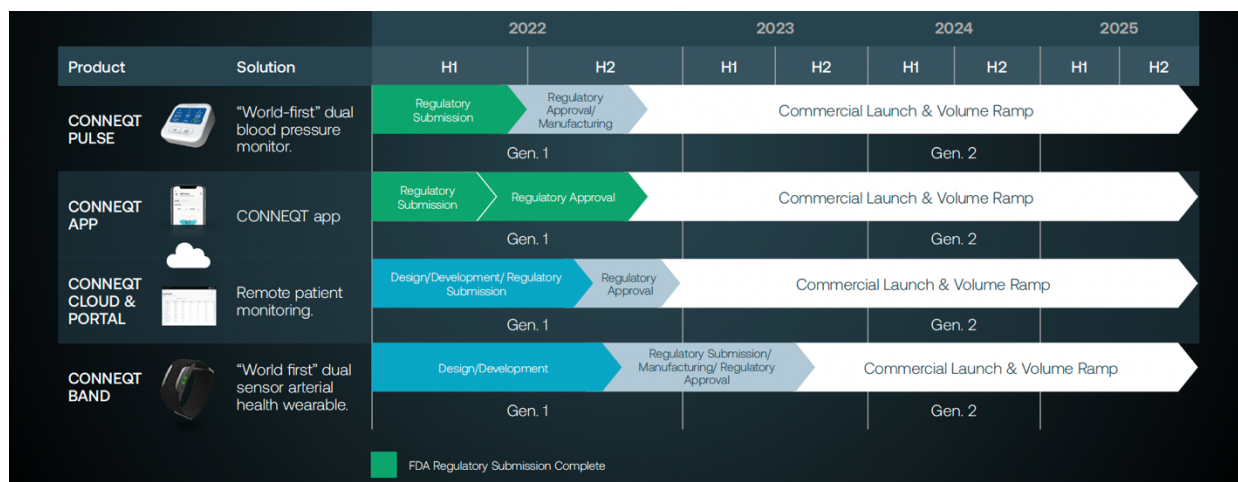
"ATCOR's market leading central aortic pressure technology has been the "gold standard" for over a decade with researchers, specialist clinicians, and pharmaceutical companies in their clinical trials. **The "Pulse" now launches that same technology into significant new healthcare markets giving physicians and patients alike deeper insights into cardiovascular health**"

Alberto Avolio
Professor Emeritus - Macquarie Medical School, Macquarie University.

During the quarter, the Company also reported the FDA classification of the CONNEQT App as a "Medical Device Data System" (MDDS), enabling the Company to proceed with its launch upon FDA clearance of the Pulse.

The Company has received its first round of comments on its clearance submission for Pulse from the FDA and has responded to those questions. At this stage there are no material issues arising from the submission. We expect 510(k) clearance for the Pulse late 2022 in advance of our participation and exhibition at the Consumer Electronics Show (CES) in January, 2023.

On the basis that the clearance for Pulse is received in late 2022, the proposed commercial product launch schedule for Pulse, would indicatively be phased as follows:



2. CONNEQT Band Update and Establishment of CONNEQT Labs

The Company continues to make good progress on the development of the CONNEQT Band, along with our partners, Fenda and LifeQ.



In order to accelerate these development efforts we have established “CONNEQT Labs”, a partnership between CONNEQT Inc, Macquarie University, and other global institutions – to be jointly located in Sydney CBD and at Macquarie University. CONNEQT Labs is the epicenter of our development and validation protocols for the Band and is composed of some of the leading global authorities in cuffless blood pressure monitoring, led by our own Chief Science & Research Officer, Dr. Ahmad Qasem.

CONNEQT Labs positions us to have a meaningful impact on the world’s largest health disorder – cardiovascular disease – and to be a leader in the development of novel solutions for identifying and managing patients at risk for multiple other disorders including preeclampsia, Alzheimer’s, kidney disease, and stroke risk.

3. ATCOR Update

ATCOR Research Sales

During the quarter research sales continued to pick up as new budgets and grants were made available to our traditional research partners and institutions. The Company is currently involved in over 250 global research studies utilizing our XCEL SphygmoCor® device.

ATCOR Clinical Trial Contracts

Our clinical trial services market continues to expand and is the focus of our ATCOR business development efforts. We are currently recruiting a new “Head of Clinical Trial Services” to lead the expansion of what 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. Our Chief Medical Officer, Dr. Steven Keston, also recently keynoted a presentation at the annual Drug Industry Association (DIA) conference in Chicago, USA on “The Use of Central Blood Pressure in Clinical Trial Development” which was attended by many of our clinical trial partners and prospects.

Our current (in negotiation) pipeline for clinical trials is over \$USD6.3m, the largest pipeline for clinical trial contract services in the history of the Company.

Major Ongoing Trials and Studies

250+

Ongoing Global Research Studies Currently in Process

\$6.3M

Clinical Trial Sales Pipeline (Proposal/Closing) \$USD6.3M

ARTERY Society



CARTESIAN Study

World's largest study on hypertension and COVID-19

CARTESIAN aims to explore the immediate and long-term vascular consequences of COVID-19, and ATCOR's SphygmoCor® XCEL was selected to assess subjects' central pressure hemodynamics.

Andwin Scientific



Andwin Trial

Andwin is a 2022 initiated trial between Andwin Scientific, Syneos Health and cigarette and tobacco manufacturer, Philip Morris.

ATCOR's XCEL device is to be used in multiple endpoints for the trial including determination of clinically relevant arterial health outcomes based on aortic augmentation index (Aix) and arterial stiffness - key biomarkers of arterial health.

CC (Confidential)



CVD Trial

Specific Pharmacological Impacts on Cardiovascular Patients

Trial involves potentially 150 patients over a 26 month period to determine specific outcomes of novel therapies on cardiovascular disease patients. ATCOR's SphygmoCor® to be the primary outcome device for arterial health parameters.

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Other ATCOR Corporate Activity

Separate to our clinical trial efforts the Company is also aggressively pursuing 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 in the next 4-6 weeks.

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

4. Mobvoi TicWatch GTH Pro Update

Following the successful launch of the Mobvoi TicWatch GTH Pro on 1 March 2022, for customers in the United States, Australia, and New Zealand the Company has now been advised by Mobvoi that they are expanding the sale of the GTH Pro to two additional English-speaking markets, the United Kingdom and Canada.

Since the initial limited market release of the GTH Pro, positive customer reviews and feedback have been received on the Amazon website in both the United States and Australia, with the product achieving a solid “4-star +” rating during the quarter. This new expanded release by Mobvoi into additional markets is strong validation for the product and its success to date.

During the Quarter the Company also collaborated with Mobvoi to successfully launch the first software update to the Company’s “Arty Heart Health Platform” that powers the arterial health insights features on the GTH Pro.

Launched March, 2022

Mobvoi TicWatch GTH Pro with CardieX "Dual-Sensor" Technology*

TicWatch GTH Pro is the first smartwatch in the world to feature the Arty Heart Health analytics platform, incorporating Arty® Score, eCAP® (Exercise Capacity®), ArtyAge™, HSX™ (Heart Stress Index), and TruHR®.

* Licensing of Arty® Consumer Biometrics & Technology to Google-Backed Mobvoi

Tech Guide
"Mobvoi TicWatch GTH Pro can give you precise insights into your heart health"

digitaltrends
"No watch goes to the lengths to detect heart and arterial health that the Mobvoi TicWatch GTH Pro does."

androidcentral
"The one-of-a-kind cardiovascular health features make this a compelling fitness tracker."

amazon ★★★★★



5. Corporate

During the quarter, revenue in traditional medical markets was \$1.06m, and cash receipts from customers increased by 43% to \$1.52m compared to the prior quarter. The Company had a cash balance of AU\$1.46m at 30 June 2022.

During the quarter, CardieX spent \$340k on product development and operating costs on new and existing products, an increase of \$168k primarily due manufacturing costs for ATCOR medical devices. Research and development expenditure increased by \$210k to \$751k, primarily due to additional costs involved in finalising the CONNEQT Pulse development and preparation for the FDA clearance application.

Payments to related parties and their associates in the quarter were AU\$266k and all related to remuneration for services under existing services agreements, with no non-remuneration payments made in the quarter to those parties.

6. Investor Update Webinar

The Company will be hosting an investor update webinar on Wednesday 3rd August 2022 to provide an update on our business activities and provide a Q&A facility for investors. Investors can register in advance for this webinar on the link below:

https://us02web.zoom.us/webinar/register/WN_PSBjNj3GQhamPE0bqhp2uQ

Further details of this webinar will be provided in a separate ASX release.



7. CEO Comments and USA Listing Update

This quarter has seen strong progress 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.

Our pipeline for clinical trial contracts has never been greater in the history of the Company - and I see this business contributing exponential revenues for the group as we move into 2023.

As previously advised to the market earlier in the year, 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 made significant progress over the quarter to achieve this key corporate objective.

Finally, in anticipation of our FDA clearance for Pulse, we will be exhibiting in the Med-Tech Innovation Hall at the Consumer Electronics Show (CES) in Las Vegas in January, 2023. This is the perfect event to launch and showcase the CONNEQT Pulse and Eco-System on the global stage.

If any of our shareholders are attending we look forward to showing you the fruits of all our hard work.

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.

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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).