



ASX ANNOUNCEMENT

31 January 2023

## CardieX December 2022 Quarter Update

### Highlights:

- Significant new Clinical Trial Services Agreement executed with ATCOR providing a cornerstone to group revenues for the coming 2-3 financial years.
- Strategic acquisition of core assets from wearable sensor start-up Blumio, Inc.
- CONNEQT Pulse vascular biomarker monitor selected as Innovation Award Honoree at the 2023 Consumer Electronics Show (CES) in Las Vegas, NV and PC Magazine "Best in Show."
- Ongoing correspondence with the FDA - targeting 510(k) clearance for the Pulse in early 2023.
- 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 December 2022 quarter.

### **1. ATCOR Update**

#### ***ATCOR Clinical Trial Contracts***

During the quarter, ATCOR executed a significant new Clinical Trial Services Agreement for the provision of XCEL devices and data management services for a new global clinical trial.

ATCOR's XCEL device will be used by the Procurement Partner, Clinichain BV, in all phases of the global clinical trial for the determination of clinically relevant arterial health outcomes based on patented SphygmoCor® digital vascular biomarkers for the assessment of arterial health. The trial is scheduled for multiple sites around the world and will last for approximately 30 months.

This new agreement is the largest in the Company's history and is anticipated to provide total life of contract revenue in the order of twice the FY22 revenues for the entire business over, providing a strong foundation for the Company moving forward.

Having recently converted a significant portion of the clinical trial pipeline, the Company's clinical trial pipeline remains strong at over US\$7 million. An example of our clinical trial sales and business development activities include discussions with country-based Clinical Research Organizations (CROs) to integrate our SphygmoCor XCEL device data to enable expansion into new markets within highly populated and underrepresented regions for conventional clinical trials.

A new partnership was also announced between ATCOR and Invariant, a data-driven health technology company with precision AI and a comprehensive, integrated, high quality data driven platform designed to accelerate research and innovation in health care systems across the country and globally. This new partnership will allow ATCOR and Invariant to jointly conduct clinical trials and healthcare research on maternal health and cardiovascular disease to improve patient outcomes.



The Invariant partnership was announced on January 3, 2023 and will be presented during the “Future through more innovation” session at the [20th Vienna Congress](#) on January 30, 2023.

In addition, ATCOR is attending the 14th Annual Summit for Clinical Ops Executives (SCOPE) on February 6-9. Several meetings will discuss the use of ATCOR’s SphygmoCor technology across global clinical trials, expanding the footprint of ATCOR with clinical research organizations (CRO), pharmaceutical companies, and global trial site networks.

## **2. CONNEQT Update**

### ***Acquisition of Blumio, Inc.***

During the quarter, CardieX acquired the core assets of wearable sensor start-up, Blumio, Inc (“Blumio”), a Silicon Valley based developer of advanced algorithms and technology for cardiovascular sensors.

The strategic acquisition of all Blumio assets and technology follows a 3-year collaboration between Blumio and CardieX during which time the companies have demonstrated Blumio’s sensor technology to be compatible with ATCOR’s patented SphygmoCor® arterial health technology.

Blumio’s technology has the potential to significantly increase the clinical performance for CardieX’s ecosystem of heart health monitoring solutions, with the core assets and intellectual property of Blumio being in developing wearable sensor technologies that can capture a cardiovascular signal without necessitating the use of pulse pressure.

Blumio’s suite of data analytics and visualization tools will enhance the Company’s “Arty Heart Health Analytics Platform” to proactively monitor, alert, and provide actionable health insights from the CONNEQT Pulse and CONNEQT Band devices, thereby enabling physicians and patients alike to make more informed healthcare decisions.

As part of the acquisition, the Company has appointed Blumio co-founder, Catherine Liao, as Chief Strategy Officer, and Blumio’s Head of Product & Operations, Steve Braaten, as VP of Operations.

### ***CONNEQT Pulse at CES 2023***

Subsequent to period end and as part of the marketing strategy ahead of product launch, 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”).

Several months of detailed planning went towards ensuring CES was a resounding success for the Company and the event delivered on several fronts. Ahead of the event, the Pulse was selected as a **CES 2023 Innovation Award Honoree** by an elite panel of industry expert judges, including members of the media, designers, engineers and more. This year’s CES Innovation Awards program received a record number of over 2,100 submissions.

Our CONNEQT booth at CES was well attended throughout the four-day event. Our team had meaningful discussions with conference attendees representing the health industry, consumer wellness, and retailers including the Mayo Clinic, IQIVA, Google, Apple, Amazon, Walgreens, and



Best Buy. CONNEQT also received strong coverage in U.S. trade and industry publications including PC Magazine who named Pulse as one of the [best wellness tech devices of CES](#).

The recognition and coverage secured at CES will be invaluable as the Company prepares to launch the Pulse, subject to receiving the required regulatory approvals.

### ***CONNEQT Product Suite Selected for NIH Maternal Health Challenge***

The Company has also been selected for Phase 1 of the National Institutes of Health's (NIH) RADx Tech for Maternal Health Challenge in the U.S., receiving an initial US\$20,000 cash prize. As one of 15 innovators accepted into the challenge, the Company will now advance to Phase 2 of the challenge.

The Rapid Acceleration of Diagnostics (RADx®) initiative was initially developed to speed-up innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. The NIH launched the RADx Tech for Maternal Health Challenge to accelerate the development and commercialization of innovations, such as the CONNEQT Pulse and Band, that will improve health for women before, during, and after delivery.

During Phase 2, the CONNEQT suite of devices and software, will undergo a detailed review of the scientific/technological, clinical, accessibility and usability, regulatory, and commercialization potential of the technology. Innovators who are selected as winners in this phase will receive \$75,000 each and advance to the final phase of the challenge. Should we be successful in all phases of the challenge, we stand to receive up to \$895,000 in prize money.

### ***Pulse Regulatory Approvals***

The Company continued to make good progress during the quarter in relation to regulatory approvals required for the Pulse. FDA acknowledged their receipt of our application and has accepted it for review. We kicked off the interactive review process in Q4 where we are corresponding with the lead reviewer and providing additional information as requested.

We anticipate receiving clearance in the coming months. Pending 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 will also be the first complete arterial health monitor to incorporate CardieX's SphygmoCor® technology in a device for general health care professionals and patients.

### ***CONNEQT Band Update***

The Company continues to progress the development of the CONNEQT Band. During the quarter the Company completed the Engineering Validation Test (EVT) phase of the development and manufacturing process. This is the stage where the looks-like and works-like prototypes are combined to ensure all functional requirements of the product requirement are met. This is generally the most critical step as it is done with the intended materials and manufacturing process.

We have now begun the Design Validation Test (DVT) stage to perfect tools and techniques necessary to ensure that the device can be mass produced while meeting cosmetic and



environmental requirements. We anticipate this stage to be completed in the first quarter of 2023 at which point we will have product-ready devices necessary to begin necessary electronics certifications prior to pursuing clinical validation.

### **3. Corporate**

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

During the quarter, revenue in traditional medical markets was \$0.9m, and cash receipts from customers increased by 268% to \$2.4m compared to the prior quarter, primarily due to a prepayment for a new clinical trial. The Company had a cash balance of \$2.5m as at 31 December 2022.

During the quarter, CardieX spent \$349k on product development and operating costs on new and existing products. Research and development expenditure totalled \$1.2m, an increase of 42% on the prior quarter, primarily due to ongoing costs involved developing the Conneqt products.

Payments to related parties and their associates in the quarter were \$333k and all related to remuneration for services under existing services agreements.

#### ***(b) Appointment of New US based CFO***

Subsequent to period end, the Company continued to build its executive team with the appointment of Reid Yeoman as the group's new U.S. based Chief Financial Officer (CFO), commencing in January 2023.

Reid's experience as a US-based CFO of a NASDAQ-listed company is aligned with the Company's broadening focus in U.S. pharma and consumer health product markets, and is timely as CardieX seeks to put in place the required local financial processes, systems and rigor required ahead of anticipated product development and launches over the coming year.

#### ***(c) Working Capital Loan Facility***

Subsequent to period end, CardieX's wholly owned subsidiary, Atcor Medical Pty Ltd, announced it had entered into a short term working capital loan facility for up to \$880,000 with Mitchell Asset Management Pty Ltd (MAM), the same lender who currently provides the Company with related commercial financing under the Company's current R&D Loan Facility.

The new loan facility forms an important part of the Company's working capital requirements and is timed to coincide with previously announced product and development expansion initiatives.

#### ***(d) CardieX Invited to 35th Annual Roth Investment Conference***

Subsequent to the period end CardieX was invited to the upcoming 35th Annual Roth Conference, in Southern California, taking place over 12-14 of March, 2023.



This “invite-only” investment conference showcases over 400 private and public companies in a variety of growth sectors including: Business Services, Consumer / Health & Wellness, Healthcare, Resources: Oil & Gas / Metals & Mining, Technology, Media & AgTech and Sustainability/ESG.

This year’s event will consist of 1-on-1 / small group meetings, company presentations, analyst-selected fireside chats, and thematic industry panels. The event is attended by over 5,000 investors and company representatives.

#### ***(e) Upcoming Extraordinary General Meeting***

As prefaced in our 2022 AGM which was held on 30 November 2022, the Company has continued to make progress positioning the Company for a potential dual listing on a U.S. exchange.

In furthering these initiatives there is a likely need for a further shareholder meeting to be held in the coming month(s) to enable CardieX to apply for such a listing. The Company will provide notice of such a meeting once it has the required approvals.

#### **4. CEO Comments**

This has been a particularly strong quarter for the group as our traditional ATCOR business secured the largest clinical trial services agreement in the Company’s history. This achievement not only continues to validate our product and solutions offering in one of the largest clinical trial markets, vascular health, but is also expected to provide a strong financial foundation for the Company over coming years.

The recent appointment of Toni Hofhine to our ATCOR executive team, as President of ATCOR, combined with the impending 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, provides new and exciting opportunities for the ATCOR business moving forward.

I’m also excited about the momentum we’re seeing with the CONNEQT business. The recognitions from CES and NIH are testaments to both the impact and commercial potential of the product suite we are offering within the CONNEQT ecosystem. The acquisition of Blumio and appointment of Catherine Liao as Chief Strategy Officer will strengthen our go-to-market efforts by capitalizing on her technology know-how and industry relationships in cuffless blood pressure monitoring necessary to scale our offering into the remote patient monitoring and consumer markets.

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

Craig Cooper

A handwritten signature in black ink, appearing to read "Craig Cooper", written over a white background.

Chief Executive Officer

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



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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.

**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 / U.S. exchange. 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.