

ASX ANNOUNCEMENT 30 June 2023

# **CardieX Corporate Update**

### Highlights:

- Updated Agreement with SunTech Medical, Inc.
- Revenue Outlook
- Clinichain Update and Revenue Timing
- CONNEQT Pulse Market Update
- Key Personnel Changes

<u>CardieX Limited</u> (ASX: **CDX**) (**CardieX**, the **Company**) is pleased to announce a general corporate update with respect to activities across the Group.

### **Updated Agreement with SunTech Medical**

CardieX's wholly owned subsidiary, ATCOR Medical, Inc (ATCOR), has executed an updated agreement with USA-based SunTech Medical Inc. (SunTech) for the sale and distribution of the Oscar 2 Ambulatory Blood Pressure Monitor (ABPM) "with SphygmoCor inside". SphygmoCor® is CardieX's arterial waveform and vascular biomarker technology.

This replaces our previous agreement with SunTech which was executed in June 2014 and established the development, marketing and sale of the SunTech Oscar 2 ABPM "with SphygmoCor inside". Our prior agreement allowed both parties to have certain sales channel and geographic distribution exclusivities, along with a profit-sharing scheme designed to favour the party responsible for the underlying sale of the device.

The new agreement carries with it a number of key developments:

- Enabling CardieX and SunTech to jointly commercialize ABPM technologies and target a much wider global addressable market and removes the previous sales channel exclusivities and profit-sharing schemes between ATCOR and SunTech;
- Both parties are now free to market and sell the Oscar 2 ABPM "with SphygmoCor inside" in any customer channel non-exclusively and compete in good faith;
- ATCOR and SunTech will now also retain 100% of their respective profits from unit sales of the Oscar 2 ABPM; and
- Granting ATCOR the right to commercialize SunTech's 'regular' Oscar 2 ABPM (without SphygmoCor inside) on a worldwide basis, excluding certain EMEA markets where SunTech already has exclusive distribution agreements in place.

The updated agreement opens up the ABPM market for ATCOR in some of the world's largest markets by virtue of access to markets that SunTech holds regulatory registration. This includes a wider range of APAC, EMEA, Latin America jurisdictions (specifically including China, South Korea, Vietnam, United Kingdom, South Africa and Chile).

With SunTech's ABPM technology having already been registered in these markets, ATCOR's shared participation in commercialization represents a fast-track to a win-win partnership that expands both companies' footprint in these markets, as well as providing another product for us to market alongside our existing suite of devices.

#### Revenue Outlook

At this stage group revenue for FY23 is expected to be more than 7% up on the revenues achieved in FY22 excluding any potential acceleration of Clinichain revenues as discussed below.

Looking forward, we believe our clinical trial pipeline is strong, which, combined with the upcoming launch of the new CONNEQT Pulse gives us confidence that strong revenue growth will be achieved through FY24 and FY25.

#### Clinichain and Revenue Timing

As announced on 9 December 2022, ATCOR was contracted by Clinichain to provide its XCEL devices and data management services as part of a ~30-month multi-site clinical trial. Since then, CardieX has received multiple purchase orders, deployed its devices, commenced provision of services, and received in excess of \$2m of receipts under the agreement.

During May 2023, the Company was advised there were likely to be delays in the progression of the clinical trial due to changing requirements of Clinichain's underlying clinical trial customer and the Company has since been advised the clinical trial will conclude earlier than anticipated.

The terms of CardieX's agreement with Clinichain (held by wholly owned subsidiary ATCOR), provided that the provision of our Xcel SphygmoCor devices and data management services, were non-cancellable.

There are commercially sensitive discussions underway regarding how ATCOR's agreement could be finalised given the earlier than anticipated conclusion of the clinical trial, however at this time, the Company is not expecting any material changes to the agreement including the originally estimated revenues and net cash receipts from the trial.

If there was an early finalisation of the agreement, there may be a number of near-term positive changes, which may include:

- 1. Reduction in unearned revenue (last reported as a current liability of \$2,250,338 as at 31 December 2022) and a commensurate increase in current year revenue as a result of those revenues being earned;
- 2. Potential acceleration of revenue timing likely to be matched to the actual date of cash receipts.

The Company will keep the market informed as to the progress of these discussions.

### CONNEQT Pulse - Production and Market Update

As advised to the market on 26 April 2023, we have received FDA clearance on the CONNEQT Pulse (the Pulse).

## Path to Production of CONNEQT Pulse 'at scale':

Since receiving FDA clearance, we have initiated the process to mass manufacture the device, as well as actively showcasing the Pulse at tradeshows and conferences around the United States in advance of launch.

Our strategy is to build a strong pre-launch sales channel and order book as well as to establish key industry partnerships to join us in our product launch activities.

We are currently in the preparation phase for trial production before we move to mass production in the coming months. This phase includes firmware and production workflow optimization and quality control review to improve yield for mass production.

#### Path to Market for CONNEQT Pulse:

Our vision with the Pulse is to be the leading provider of home, wearable, healthcare, clinical trial, and remote patient monitoring solutions for common health disorders related to high blood pressure including hypertension, CVD, Alzheimer's disease, chronic kidney disease (CKD), and other major vascular health conditions. We believe that the use of digital vascular biomarkers will become part of the standard practice in the management of cardiovascular health, patient monitoring, and ensuring patient safety during clinical trials.

CONNEQT Pulse incorporates our SphygmoCor vascular biosensing technology. The Pulse offers dual blood pressure (central and brachial) and other advanced measures of vascular health not available with traditional blood pressure monitors.

Marketing our product will require a focus on the key market segments (home, wearable, healthcare, clinical trial, and remote patient monitoring solutions) and educating these cohorts on the benefits of the CONNEQT Pulse and our vascular biomarkers.

Examples of activities we have initiated since FDA clearance are:

- April 27/28 Cambridge, UK. International Maternal Hemodynamics Workshop at Cambridge
  University. We presented the Pulse to a group of ~50 researchers across Europe and North
  America who are involved in maternal hemodynamics.
- May 4 Virtual. MedTech Innovator Virtual Pitch. We presented the Pulse and its value proposition in maternal health to a panel of 25 judges and was subsequently selected as 1 of 61 companies for this year's MedTech Innovator accelerator cohort, beating out approximately 1,100 companies. A video of our 6-min presentation & product demo is available on our Twitter account today @CardieXLimited.
- May 6 Houston, US. We presented the Pulse to the <u>Maternal-Fetal Medicine physicians and</u> <u>fellows at the UTHealth</u>, part of Texas Medical Center (world's largest medical complex with 10

million patient visits a year).

- May 9 Washington DC, US. We presented the Pulse at the *Innovative Approaches to Improve Maternal Health* event hosted by the *National Institute of Health*.
- May 18 Orlando, US. American Academy of Anti-Aging Medicine (A4M). Dr. Joseph Rafaelle, a
  long time SphygmoCor user and advocate, presented a talk on how the Pulse can be leveraged
  in assessing and reversing arterial ageing to an audience of over 150 clinicians. We also had a
  booth over 3-days at the event.
- May 28 Sydney, Australia. Chief Strategy Officer Catherine Liao joined cardiologist *Dr Ross* Walker, host of the *Healthy Living* weekly radio show, on air to discuss the CONNEQT Pulse. You
   can tune in to the interview, starting at the 59 min mark at the link on our Twitter account
   posted today @CardieXLimited.
- June 13 Virtual. CardioSensor conference. We presented our foundational technology for noninvasive assessment of vascular biomarkers to an audience of ~100 clinicians and medical device technologists representing companies including Bayer, Kaiser Permanent, and Johns Hopkins.[ A video of our presentation by Chief Strategy Officer, Catherine Liao, is available on our Twitter account today @CardieXLimited.]
- June 14-16 San Francisco, US. *Medtech Innovator & Wilson Sonsini Med Device Conference* where we had opportunities to showcase the Pulse to over 300 attendees as well as one-on-one demonstrations to investors.
- June 16/17 Iowa City, US. North American Artery conference. Dr. Alberto Avolio hosted a learning luncheon to ~60 delegates who are involved in hemodynamics research.
- June 25-29 Boston, US. We are currently attending the *Drug Information Association (DIA) global annual meeting this week* with our partner Datacubed to jointly pursue opportunities in decentralized clinical trials.

### **Blumio Asset Acquisition**

As announced on 16 November 2022, CardieX agreed at that time to purchase certain assets of Blumio, Inc (Blumio) pursuant to an Asset Purchase Agreement between the parties.

The majority of the consideration for this acquisition was agreed to be by way of CardieX shares ('being either Ordinary Shares or the equivalent value of American Depository Interests (ADR's)), to be issued to Blumio or their nominee at their direction, and payable subject to the following terms:

- 50% on 15 June 2023 at the closing price of CardieX Ordinary Shares or ADR's; and
- 50% on 15 March 2024 at the closing price of CardieX Ordinary Shares or ADR's.

The Asset Purchase Agreement further provided that in the event that CardieX had not been listed, or authorized to list, on the Nasdaq exchange prior to 15 June, 2023 or 15 March, 2024, then the share consideration otherwise due at those respective dates would be paid in cash.

The parties have now agreed that the full consideration owed under the Asset Purchase Agreement will be paid by way of CardieX Ordinary Shares or ADR's on 15 September, 2023, with none of the consideration to be paid in cash.

The Company has filed an Appendix 3B to note this amended later this day.

#### Personnel Update

Our US-based CFO, Mr. Reid Yeoman, has unfortunately had to resign from the Company with immediate effect due to personal health reasons. The Company hopes for a strong and fast recovery for Reid and thanks him for the great work he has done with us over the last six months.

The Company also notes the recent termination of Toni Hofhine as President of Clinical Operations within our ATCOR subsidiary.

Following Reid's resignation the Board has commenced a search for a full-time US-based CFO, and in anticipation of an upcoming appointment, have prudently reorganized the finance and Company Secretary roles. The finance function is currently resourced using a combination of internal and external accounting and finance services, noting that the CFO role/function has previously been provided on an outsourced basis by Mr Jarrod White and Mr Nicholas Marshall for over four years prior to Reid's appointment. The Board has reinstated the outsourced CFO function on an interim basis during the period of the CFO search. Messrs White and Marshall have both resigned from their respective roles as Joint Company Secretary effective immediately, to better delineate the financial and governance requirements of the Company at this time.

Moving forward and effective immediately, Ms Louisa Ho has been appointed as Company Secretary.

**Craig Cooper Chief Executive Officer** 

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

- ENDS -

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#### **About CardieX**

CardieX is a global medical technology company focused on developing and marketing products and solutions for vascular health. Its <u>ATCOR</u> subsidiary is a world leader in medical devices and arterial biomarkers for hypertension, cardiovascular disease, and other vascular health disorders based on the Company's "gold standard" SphygmoCor® central blood pressure technology. CardieX's <u>CONNEQT</u> 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).

#### **Cautionary Note Regarding Forward-Looking Statements**

CardieX cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on CardieX's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential market opportunity for ATCOR based on updated agreement with SunTech Medical; management's revenue outlook; management's expectations regarding ATCOR's agreement with Clinichain; and management's vision for the CONNEQT Pulse and related potential market opportunities. The inclusion of forward-looking statements should not be regarded as a representation by CardieX that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in CardieX's business. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and CardieX undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof.