



ASX ANNOUNCEMENT

30 July 2020

CardieX June 2020 Quarterly Update

Highlights:

- **Major Milestone achieved in the development of CardieX's Wearable Sensor Technology:**
 - In a research breakthrough, ATCOR extracts waveforms from PPG sensor, facilitating use of the Company's core SphygmoCor® technology in wearables.
 - Development allows CardieX to advance to next phase of JDA with Mobvoi.
 - CardieX submits US patent application for its PPG sensor technology and multiple new trademark applications.
- **CardieX's central blood pressure technology to be integrated into standard brachial BP monitors.**
- **Significant progress achieved with Partnerships and Commercialization:**
 - CardieX development partner Blumio signs deals with Switzerland-based pharmaceuticals and diagnostics giant, Roche, and Germany-based semiconductor manufacturer, Infineon Technologies.
 - CardieX progresses on Sensor Development Kit for third-party wearable device makers.
- **CardieX restructures its agreement with and investment in inHealth Medical.**
- **ATCOR technology selected for use in the first international clinical trial to assess arterial stiffness impact in COVID-19 survivors, commissioned by the ARTERY Society.**
- **Strong financial close to end of financial year 30 June 2020:**
 - Appendix 4C lodged this day shows a strong operating quarter
 - Total receipts for June 2020 \$1.54m with a total of \$5.11m for the fiscal year
 - Funding through the June quarter from debt facility and US PPP funding
 - Closing cash for the year of \$2.06m noting over \$3.2m in additional cash received during July from inHealth investment reorganisation and placement
- **Board Appointment of Jarrod White as a Director as well as key development team appointments.**

CardieX Limited (CardieX, the "Company") is pleased to provide an update on its activities during the June 2020 quarter.



Wearable Sensor Technology Development:

CardieX's strategy is to integrate its FDA (US Food and Drug Administration) cleared SphygmoCor® technology into the spectrum of smart wearable devices for consumer and medical settings. This involves a complex and significant technology and engineering effort in order to extract waveforms from a wearable (PPG-based or otherwise) sensor that correlate well with those extracted by its current FDA-cleared device, which is considered the gold standard for measuring an aortic arterial pressure waveform with cardiovascular features.

In April, CardieX subsidiary ATCOR completed a major milestone in the development of its wearable sensor technology and derived a series of unique heart and arterial health features from a PPG sensor which have the potential to significantly expand the clinical and consumer applications of the SphygmoCor® technology. As a result, CardieX will now proceed with the next phase of its FDA with Mobvoi, Google's Wear OS partner in China). The Company has also submitted US patent applications for its proprietary technology for PPG sensors as well as a number of trademark applications for the medical and clinical data sets that the Company has been able to extract so far.

The ability to extract a waveform from a PPG sensor— capturing the blood pressure waveform from the pulse measured in the fingertip-- that is of sufficient quality to be utilized with CardieX's SphygmoCor® signal processing opens the path to the further measurement of a number of other clinically relevant vital signs. Consisting of LEDs and photodetectors, PPG sensors are one of the most widely used optical sensor arrays on wearable devices, and they are frequently used to develop consumer-grade biometric capabilities, such as heart rate measurement and other general fitness features.

The sensors in most consumer-grade wearables are usually represented by a combination of red, green and infrared light-emitting diodes. The ATCOR team was able to extract signals from a PPG sensor that correlate well with waveforms extracted by SphygmoCor® technology. Previously this had only been possible with a brachial cuff on a patient's arm while using the SphygmoCor® technology.

ATCOR completed internal human studies (13 subjects, 157 signals, with an age range of 20 to 65 years, with results distinguishing between healthy, non-healthy, young and elderly participants) and in conjunction with Macquarie University (Dr. Mark Butlin, Department of Biomedical Sciences). ATCOR has initially determined four unique and proprietary heart and arterial health features, which are believed to have been extracted from a PPG sensor for the first time (see below). This represented Phase 1 of the Company's PPG program, and ATCOR's engineering team is now working to complete Phase 2, which includes development of multiple new clinically relevant features for blood pressure management.

All medical devices in the USA need to obtain 510(k) clearance from the FDA; however, there is a fast track process for clearance in the normal course for technologies that are based on previously cleared technologies such as CardieX's SphygmoCor® technology so CardieX is well placed to achieve that clearance using the fast track process. CardieX is the only company that has FDA clearance for measuring central blood pressure, arterial stiffness, and other proprietary cardiovascular parameters non-invasively in adults. The SphygmoCor® technology has more than 4,500 installations globally and is used by leading research and pharmaceutical companies, such as Bayer, AstraZeneca, GSK and others.



Mobvoi Development Partnership:

CardieX also has a Joint Development Agreement (JDA) with Mobvoi for the development of novel and proprietary health technologies, applications and features to be integrated into Mobvoi's next generation smart wearables. Mobvoi is Google's official Wear OS partner in China. As a technology unicorn based in Beijing, Mobvoi boasts a stable of well-known investors, including Google, Volkswagen, ZhenFund and Sequoia Capital China.

The Company's partnership with Mobvoi is focused on the use of PPG sensor to derive unique consumer health functions for integration into Mobvoi smartwatches.

During the quarter, ATCOR presented the results of its PPG research and engineering efforts to Mobvoi (as outlined above).

CardieX is now looking at expanding the opportunities under the JDA to new markets and other applications, such as the provision of data and related technologies to Mobvoi under a "services & subscription model". More details will be provided as those discussions progress.

Mobvoi and CardieX continue to operate remotely with little impact on day-to-day operations resulting from current global conditions.

New Patent and Trademark Applications:

On 1 June, CardieX submitted a US patent application in support of its wearables strategy. Provisional application 63/031,645 describes a system and method of measuring medically reliable heart & arterial health indicators from a plethysmogram ("PPG") light sensor on a wearable device when a user places their finger on the sensor. The determination of a heart pulse with significant heart and arterial health indicators by way of the patent could previously only be obtained either invasively or through a medical device in a clinical setting.

The biometric data captured by the PPG sensor correlates well with waveforms extracted by The Company's gold standard SphygmoCor® algorithms, and the derived feature include:

- Heart Stress;
- Heart Age;
- Exercise Capacity; and
- Heart Rate-Plus.

As the most widely used sensors on wearables, PPG sensors are incorporated into a broad range of devices from the world's leading technology companies, including Apple, Samsung, Garmin, Mobvoi, Fitbit and others.

The first application of the patent will likely be on Mobvoi smartwatches, but CardieX also plans to license the technology to other wearable technology companies and include it in the Company's own medical and consumer wearable devices.

In parallel with product development efforts, CardieX has also applied for trademark protection for up to 20 proprietary new parameters and product/service brands in multiple geographies around the globe.



Integrating Central Blood Pressure into New Home BP Monitors:

CardieX is developing a vision for its Complete BP™ solution, a powerful combination of brachial and central blood pressure which gives clinicians and consumers alike a more complete picture of blood pressure.

In late June, as part of the development of an ATCOR home BP monitor, CardieX programmed and shipped prototype chips to ODM partner, Andon, who will commence integrating the Company's central blood pressure technology into a reference design for a standard brachial BP monitor.

In other blood pressure-related research, CardieX has developed research software that enables collection and preliminary processing of individual BP measurements via a PPG sensor. The Company is collaborating with Macquarie University, its research partner in Sydney, Australia, to conduct data collection within social distancing guidelines.

ATCOR ABPM Technology Recommended for MSAC Reimbursement:

A recommendation in June 2020 from the High Blood Pressure Research Council (HBRCA) that Australia's Medical Services Advisory Committee (MSAC) and the Federal Minister for Health approve reimbursement of ambulatory blood pressure monitoring (ABPM) through the country's Medicare Benefits Schedule (MBS) could increase demand for the Oscar 2 with SphygmoCor Inside ABPM in Australia. The Oscar 2 is a 24-hour ambulatory blood pressure monitor (ABPM) by SunTech Medical that includes the Company's SphygmoCor® technology inside. This product is sold exclusively by ATCOR in Australia.

HBRCA recommends that reimbursement be made available for diagnosis of hypertension in patients who have measured clinic-based blood pressure between 140/90 mmHg and 180/110 mmHg, with reimbursement up to once every 12 months for individuals who have not commenced antihypertensive medication. The average recommended fee is A\$107.60.

HBRCA estimates that more than 700,000 ABPM procedures will be required over the first three years of coverage.

The Oscar 2 device adds ATCOR's proprietary central blood pressure algorithms to a standard ABPM, providing the benefits of central pressure waveform analysis for enhancement and individualization of patient care over standard blood pressure monitoring.

CardieX PPG Sensor Development Kit:

Reaching the first major milestone in the Mobvoi technology partnership was also a significant step in the development for the CardieX Sensor Development Kit (CSDK), because it has demonstrated the ability to extract unique cardiovascular health features from a PPG sensor – a technology accomplishment that has not been achieved to date. CardieX is moving forward with the CSDK, which includes a reference design for PPG sensor integrating the Company's proprietary algorithms.

This CSDK would allow other device makers, such as Garmin, Apple, and Fitbit, to assess and incorporate CardieX technologies into their devices, given that they use the same PPG sensor technology that forms the basis of our CSDK.



The first release of the CSDK will include the algorithms announced to the market in April 2020. The next phase of the CSDK will include further advanced algorithms and features that will become commercially available in Q2 2021 for licensing to third-party device manufacturers.

Strategic Partnership with Blumio Continues to Add Value:

As noted previously, CardieX has several ongoing partnerships and development efforts, including a Co-Development Agreement (CDA) with Silicon Valley-based Blumio that integrates the Company's proprietary technology into the Blumio radar sensor. The partnership comprises two main parts:

1. A Co-Development Agreement (CDA) that provides for the integration of SphygmoCor® technology into the Blumio radar sensor, allowing for a unique and patented set of cardiovascular data features to be extracted by the Blumio sensor; and
2. The Company's investment in Blumio for 7.5% equity ownership with the potential to increase to 10% (for no additional cash investment) based on the achievement of certain additional milestones.

CardieX continues to integrate its algorithms and technology into the Blumio sensor under the CDA and has met all important milestones and technology standards to date. For its part, Blumio recently completed its first-generation sensor development kit as one of the major milestones under the CDA.

The Blumio Sensor Development Kit consists of a radar sensor board, a wearable enclosure and a small processing unit running algorithms that generate an arterial waveform in real-time. This is the first step towards making Blumio's sensor technology commercially available to device makers as the development kit enables their partners—including CardieX—to execute product development efforts in parallel.

Other Large Global Players Join In:

Recognizing the importance of the global market opportunity for the Blumio sensor, Swiss healthcare technologies company, **Roche**, selected Blumio for a pilot project to explore the feasibility of integrating Blumio's sensor technology into Roche's next-generation diagnostics devices. As part of this pilot project, Blumio then introduced global semiconductor manufacturer **Infineon Technologies AG** into the dialogue with Roche, as Infineon currently manufactures a key component used in diagnostics devices from Roche.

These discussions led to Blumio signing an agreement with Infineon (separate from its pilot agreement with Roche) to co-develop a wearable, non-invasive blood pressure sensor by 2021 based on Infineon's XENSIV™ radar chipset. The new sensor has the potential to disrupt the USD45 billion market for wearable cardiovascular monitoring devices by enabling continuous and precise BP measurement without a cuff.

Blumio's partnership with Infineon will further promote the accelerated commercialization of Blumio's technology in one of the largest healthcare technology markets. Upon successful completion, a kit combining Infineon's radar chipset and development board with Blumio's software and algorithms will be released to consumer and medical wearable device makers to integrate into their blood pressure monitoring devices.



All boats will rise as a result of this partnership between Infineon and Blumio, and CardieX will be working hard to further refine the integration of its SphygmoCor® technology into the Blumio sensor as development efforts continue. Ultimately from a commercial perspective, the Company's strategy is to continue working with Blumio in parallel to the Infineon/Blumio efforts, so that our algorithms are supported and included in the commercial product of the parties.

The Infineon Development Agreement and the Roche pilot project create the foundation for global development and application of Blumio's sensor technology through the combined networks of both Roche and Infineon.

ATCOR Support for Pharmaceutical Clinical Trials Continues Apace:

ATCOR generates significant revenue each year in our clinical trials business unit. We contract with pharmaceutical companies for the use of SphygmoCor® XCEL devices and the provision of core lab and data management services for clinical trials — providing end-to-end service that ultimately delivers clean datasets to study sponsors. SphygmoCor® technology has been utilized in pharma trials across the therapeutic spectrum, participating in clinical trials for hypertension, diabetes, heart failure, psoriasis, renal disease, and many other disease states. We are currently contracted for clinical trials that will enroll over 2,000 patients at more than 150 clinical trial sites in 20 countries across the globe.

ATCOR Technology to Feature Prominently in COVID-19 CARTESIAN Study:

In a significant validation of our technology, our SphygmoCor® XCEL device was selected by the European ARTERY Society to exclusively measure central blood pressure and augmentation index in the CARTESIAN study — the first clinical trial to focus on the impact of COVID-19 on arterial stiffness and central hemodynamics.

The longitudinal, multicentre study will recruit individuals with recently confirmed infection by SARS-Cov-2, who will undergo two visits – 3 to 6 months and 1 year after COVID-19 diagnosis. During each visit, assessment of carotid-femoral pulse wave velocity and central hemodynamics will be performed.

Ancillary studies will explore additional biomarkers of accelerated vascular aging. The CARTESIAN study aims to identify early predictors of cardiovascular events and inform better preventive care in a post-coronavirus world.

Data from this study will also drive our product development going forward as we seek to refine our medical and consumer devices to better identify COVID-19 risk factors.

Restructuring of Agreement with and Investment in inHealth Medical Inc:

After the end of the quarter, CardieX announced it had restructured its partnership with and investment in inHealth Medical, following significant developments in both businesses since partnership commenced in 2018.

Since then, the inHealth business has developed significantly. The company has signed major global corporations as partners and clients and continued to grow its private practice, partnerships and enterprise business revenues. In addition, inHealth appointed experienced telehealth veteran and technology leader, Harry Kim, as CEO and Chairman, and three new executive hires have significantly enhanced the management team.



Interest in US telehealth businesses is strong, and inHealth is well-positioned to raise new capital at significantly favourable valuations from US-based investors and strategic parties, a process the company has already launched.

CardieX and inHealth management teams agreed to restructure the partnership and investment to provide the best capital structure to facilitate new investment, while ensuring that management and founders are appropriately incentivized to drive growth and continued success.

Key changes were reducing the outstanding convertible note to USD2.5 million by repayment of USD0.5 million, extending the maturity date to 1 July 2021, and exchanging the option to move to 50.5% for the issuance of 1% of the fully diluted equity of inHealth. This results in CardieX increasing its shareholding to 8.7% and up to 37%, depending on the conversion of the convertible note and before further capital raising.

Furthermore, CardieX and inHealth agreed to an ongoing Collaboration Agreement to develop hypertension and cardiovascular programs for the products, solutions and markets addressed by both parties. These include the current inHealth/CardieX “Central Blood Pressure” research project using SphygmoCor® XCEL device, “Telemedicine to Reduce Cardiovascular Disease Risk: A Randomised Clinical Trial”, with Dr. Jeremy McConnell from Florida, USA, as the lead investigator. Under the ongoing Collaboration Agreement, it is expected that a number of other projects may be undertaken on a commercial arms-length basis.

COVID-19 Update on Operations:

The CardieX team is spread throughout its functional HQs in Australia, the United States, and China. CardieX management and staff have all continued to make progress tirelessly during COVID-19 restrictions –working remotely via video-conferencing and other virtual collaboration tools without any loss in productivity.

Team members are now carefully migrating back to the office while maintaining appropriate physical distancing and mask-wearing protocols to protect the health and safety of the entire team.

While restrictions slowed down certain operations, such as in-person sales calls, on-site consultations, and live marketing events at industry conferences and trade shows, CardieX accelerated the ongoing ramp-up of its digital marketing strategy. Highlights include:

- eMarketing and hybrid email/phone campaigns to qualify warm leads, update our CRM database, and offer sales promotions to existing customers and new prospects languishing in COVID-19 limbo.
- Addition of high-value content to both the CardieX and ATCOR websites, including recent research on the correlation between chronic hypertension and cognitive impairment as well as articles exploring the cardiovascular complications of COVID-19.
- Launch of a new webinar series in collaboration with leading industry partner, The American Academy of Anti-Aging Medicine (A4M). The first webinar featured noted cardiologist and anti-aging expert, Dr. Mark Houston, discussing “New Approaches to Cardiovascular Aging—Central Pressure Waveforms & Arterial Stiffness Assessment.” Registrations and attendance were significant and follow-up interest has been solid to date.



- Launch of a new series of video interviews, entitled “No Pressure”. In the first of this series, ATCOR Sales Director, Ric Ruffhead, sat down with Dr. Lee Marcus, a preventive cardiologist from New York, to discuss the challenges of practicing cardiovascular medicine at the US epicentre of COVID-19, and the likely impact on his practice in the future.

Strong Financial Close to the 2020 Fiscal Year and Commencement of ASX Quarterly Reporting:

Appendix 4C Reporting from June 2020 Onward

During the quarter the Company received notice from the ASX that it would be required to commence reporting under the ASX Appendix 4C quarterly reporting requirements from the June 2020 quarter onward.

The below comments should be read in conjunction with the Appendix 4C lodged this day.

Strong Quarterly and Overall Fiscal 2020 Performance

The Company is pleased to report total receipts for June 2020 of \$1.54m with a total of \$5.11m for the fiscal year. This growth in receipts is largely attributed to the Company’s increasing success in winning pharma study contracts that have previously been announced to the market with Bayer and other major pharmaceutical companies.

June 2020 net operating outflows of \$220k for the quarter were the result of a strong quarterly revenue performance combined with controlled cost reductions and refocusing of expenditures during a period of diligent financial management as the Company reviewed its cost base during the March – June period.

Strengthened Cash Position and Balance Sheet

Prudent management of cash outflows and commitments to reduce the core operating run rate has assisted in a **strong closing cash balance** for the year of \$2.06m.

This was also assisted by access to the previously announced debt facility of \$1.5m and access to the US Payroll Protection Plan (PPP) funding program of \$252k (US\$173k). The Company believes based on advice to date that the PPP proceeds in the June 2020 quarter will be forgivable by the US government in due course and recognised as a government grant.

Notwithstanding the strong year end position, subsequent to the year end it is noted that there have been **material improvements** to the Company’s cash position, **totalling in excess of \$3.7m**, due to the following events announced during July:

- Receipt of \$715k (US\$500k) from inHealth following a reorganisation of the Company’s convertible note investment;
- Announcement of a \$2.5m placement to new strategic investors to be completed by end of July;
- Confirmation of planned EGM to approve previously announced \$500k additional investment by C2 Ventures Pty Ltd (related party to Chairman Mr Niall Cairns and CEO Mr Craig Cooper).



The Company's robust 2020 performance combined with the recent strengthening of the balance sheet at the start of fiscal year 2021 comes at the appropriate time as the Company directs its focus to the previously announced new product development projects to expand and renew the Company's product offering.

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

Board and Management Appointments:

CardieX announced the Board appointment of **Mr. Jarrod White as a Director** of CardieX in May.

The appointment of Mr. White as an additional Sydney-based Director allows the Company to be more responsive to the local business needs and requirements and will enhance the Board's capacity as the Company grows its presence, product range and revenue internationally in the coming months and years.

Jarrold has been the Group CFO and Company Secretary of CardieX since early 2018, and he will continue in both roles with Philip Leighfield appointed as Joint Company Secretary to assist in operational compliance given the expansion of Jarrold's role.

Mr. White's appointment as a director is also recognition of his significant contribution to the Company over his tenure to date.

In addition, CardieX made several significant advances on our digital health solutions strategy. To drive and accelerate that strategy, CardieX made several key hires in Q4:

- **Dan Posnack, Director of Product Development - Digital Health**
Broadly experienced in all aspects of product development from ideation to commercialization, Dan leads digital product development (cloud, portal, apps) and other associated initiatives, including EMR integration and reimbursement strategy.
- **Sameer Molvi, Senior Engineering Program Manager**
Sameer focuses on project management across our new device strategy, orchestrating a broad spectrum of product development deliverables.
- **Scott Kolek, Senior Software Engineer**
With more than 25 years of experience developing software for multiple verticals, including IoT and IoMT, Scott drives front-end to middleware to backend development.
- **Ehad Akeila, Senior Firmware Engineer**
Ehad leverages his experience with Nokia, Broadcom, and Nanosonics to develop world-class firmware, starting with CardieX's new home BP monitoring device.
- **Rebecca Davis, UI/UX Designer**
With a background in digital health and IoT/IoMT, Rebecca drives the UI/UX design of easy-to-use apps and clinician portals that form a streamlined healthcare eco-systems.

**Outlook:**

Significant progress was achieved during the quarter in relation to technological and commercial development as well as product expansion of the Company's proprietary SphygmoCor® technology. The continued development of wearable sensor technologies in health-related devices provides a large market opportunity for CardieX in clinical and consumer applications, as does our future product portfolio of consumer, home, and clinician-focused medical devices.

Our strategy also continues to focus on developing the first "uncalibrated", non-invasive and cuffless wearable sensor for monitoring blood pressure and other cardiovascular health vital signs – which is considered to one of the "Holy Grails" in wearable health monitoring. We look forward to updating the market on further progress.

Craig Cooper
CEO & Managing Director

Authorised for released by the full Board of Directors

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About CardieX

CardieX is a global health technology company that develops digital and device based solutions for large-scale population health disorders. The Company's XCEL device is the world leader in measuring "central blood pressure" which is considered essential for the management of hypertension and related cardiovascular disorders. XCEL was developed and is marketed by CardieX's 100% subsidiary, ATCOR.