

**ASX ANNOUNCEMENT**

# WEARABLES & BLUMIO UPDATE FROM CEO OF CARDIEX

*5 June 2019*

**CARDIEX ACHIEVES SUCCESSFUL MEASUREMENT OF CENTRAL BLOOD PRESSURE  
USING CARDIEX ALGORITHM AND BLUMIO SENSOR**

(DEBORAH STUDY, MACQUARIE TRIAL AND JOINT DEVELOPMENT AGREEMENT UPDATE)

I wanted to update my fellow shareholders on:

1. the objectives and progress of both the Deborah Heart & Lung Center Study for the Blumio sensor as well as activities being pursued in accordance with the Joint Development Agreement (JDA) between CardieX and Blumio;
2. our competitive positioning in regard to the commercialization of a wearable blood pressure sensor;
3. a major milestone that we have now achieved under the JDA in the measurement of central pressure and blood pressure variability through the Blumio sensor using CardieX technology and algorithms – a significant step forward in our path to commercialization; and
4. the next steps and milestones for CardieX and Blumio going forward.

As a reminder, both companies intend to commercialize a wearable, non-invasive, sensor-based and cuff-less blood pressure (BP) monitor that incorporates the proprietary and FDA-cleared SphygmoCor® technology for measuring central blood pressure (cBP) from CardieX.

**Blumio Investment and Joint Development Agreement (“JDA”) Focus**

As previously outlined to shareholders, the commercialization of a wearable, non-invasive, sensor-based and cuff-less BP monitor is considered one of the holy grails of medical technology development. A report from [Grand View Research](#) in May 2017 forecasted the market for BP monitoring at nearly \$12 billion by 2025, with home BP monitoring alone being a **\$1 billion market by 2020**. Other commentators in the space have estimated the market to be at least \$40 billion if including all potential applications for continuous monitoring with a non-invasive and cuff-less wearable device (CNBC, 2019).

**Presently, there are no FDA-cleared cuff-less and non-invasive BP-sensing devices available on the market,** although there are some non-FDA-cleared consumer devices (mainly from China) that provide BP “estimates” derived from heart rate as well as select devices that incorporate traditional oscillatory BP monitoring, such as the recently announced Omron BP watch with inflatable cuff – FDA-cleared but not cuff-less.

To date, no company has addressed the need for clinically validated, FDA-cleared, wearable and cuff-less BP monitoring, and that is the foundation of our partnership with, and investment in, Blumio. This is also where we see a significant commercial and financial opportunity for CardieX as a company.

However, we are not only working with Blumio on their wearable BP sensor solution, we are also taking it one step further under our JDA, by seeking to replicate the same level of data fidelity extraction in a wearable signal that we obtain from our current FDA-cleared SphygmoCor® XCEL device. This is the working foundation of the collaborating development teams at CardieX and Blumio in Sydney and Silicon Valley, respectively. The opportunity here is not only to develop a BP-sensing wearable, but one that also measures cBP, which is the vascular pressure that is read at the “organ level” – mainly the heart, kidneys, and brain, and clinically significant cardiovascular indicators related to major heart diseases

We believe that this level of detailed cardiovascular data in a wearable device has the potential to significantly and meaningfully disrupt the century-old paradigm for diagnosing heart and other vascular-related disorders, effectively replacing the current home-, clinician-, and hospital-based systems of managing cardiovascular and related disorders.

A significant number of global institutions, research initiatives, and policy directives support our efforts in this regard, including The Lancet Commission, who are conjointly calling for arterial stiffness, cBP, and other features that are available from our proprietary cBP technology to be used going forward as a key component in the advancement of cardiovascular disease management.

Indeed, with the scale of this opportunity, our development efforts under the JDA comprise an equally significant, if not a greater opportunity for us than our equity investment in Blumio, especially given that CardieX will own the IP and algorithms that we derive from these development efforts in regards to the derivation of cBP from Blumio’s sensor (see more on this below under “**JDA Activities Update**”).

### **CardieX Opportunity**

With the above in mind, I also want to be very clear about the overall opportunity for CardieX shareholders.

It is our strong belief that regardless of which competitor(s) solves the single wearable BP solution first, they will not be able to extend that opportunity into cBP and other related clinical parameters with the same degree of accuracy and clinical support that is derived from our SphygmoCor® technology.

For this reason, we have been focused internally on multiple additional partnerships and opportunities to incorporate SphygmoCor® into the next generation of devices, independent of the partnership we currently have with Blumio. This is partly the reason for our recent product and technology roadshow and partnership meetings in China throughout March 2019.

Make no mistake, all major consumer tech companies are on a quest to be first-to-market with a BP-sensing wearable device – be it Apple, Samsung, Microsoft, Google, or Amazon. All these major players have invested in dedicated healthcare teams internally looking to build a set of solutions, consumer applications, and monitoring devices around large-scale population health disorders. Our competitive advantages are multifaceted and well-protected:

1. a 15-year legacy in BP data extraction and signal processing algorithms that has become the “gold standard” in this field;
2. existing FDA-cleared technology that non-invasively measures cBP using pulse wave signals (that can be applied across multiple devices);
3. an extensive IP portfolio with patents and trade secrets that cover extraction of cBP and other related cardiovascular indicators;
4. new sensor-based technology (through our partnership with Blumio) that has shown positive data extraction to date based on the trials at Deborah Heart & Lung Center and Macquarie University; and, importantly
5. completion of an algorithm that has successfully measured cBP, clinically significant cardiovascular indicators, and BP using the Blumio sensor (see below “JDA Activities Update”).

#### **Deborah Heart & Lung Study Update – Ongoing Success to Date**

As shareholders are aware, Blumio commenced BP data extraction from patients at the Deborah Heart & Lung Center in November 2018. The objective of the study is to compare traditional BP data output (through an invasive arterial line) with Blumio’s sensor algorithms and to use that data to refine Blumio’s algorithms for clinical use.

Since starting the study in November 2018, the research team at Deborah continues to successfully collect reference blood pressure data from subjects. Patients are consented during their pre-surgical health check-up, and data collection is done after they are out of the surgery and recovering in the ICU.

To increase the rate of patient throughput, Blumio has also been opening the study to patients outside of the ICU, who rely on cuff measurements collected once every 5 minutes (versus once per minute in the ICU) as the reference data. The trade-off in data resolution allows Blumio to increase throughput and complete patient enrolment sooner.

The trial and data aggregation is continuing and Blumio will extend, curtail, or finish the study at an appropriate stage when their team believes it has completed enough data extraction to achieve the adequate refinement of the required algorithms, as that is the ultimate objective of the study. Presently, Blumio has not reached this stage, but a call will most likely be made on that date shortly in order to ensure that we are on track for meeting our 2019 milestones.

#### **JDA Activities Update**

Shareholders are also aware that we also have a separate 50/50 Joint Development Agreement (“JDA”) with Blumio in respect of joint development activities surrounding a combined BP and cBP wearable device. This is separate from our equity ownership in Blumio (via a Convertible Note).

Our present focus under the JDA is to use the Blumio sensor for non-invasive measurements in three commercial use cases:

1. Arterial age, exercise capacity, and cardiac load (i.e. a “Quantified Athlete” use case);
2. Estimation of BP/cBP and related cardiovascular indicators with a one-time calibration (i.e. a 24-hour continuous blood pressure/ABPM use case); and
3. Continuous BP and cBP values estimation (i.e. a cuff-less use case for both BP and cBP).

The JDA with Blumio provides for a series of milestones and development stages as we jointly progress forward and I am pleased to provide shareholders with the following update:

### **JDA Stage 1 – Macquarie University Trial - Completed**

In the Macquarie University trial (previously announced to the ASX), CardieX and Blumio conducted 17 sessions across 15 subjects. Each session contained three recordings during control conditions and two BP altered manoeuvres of three to five minutes in length (which basically means moving peoples position to induce BP changes). Each recording was captured on different equipment for comparison purposes with the Blumio sensor, which has 64 channels of data for analysis. Ultimately this resulted in a minimum of 3,264 (i.e. 17 x 3 x 64) channels of data that required analyses.

During Phase 1 (up to the end of March 2019), we had processed 15 sessions (i.e. more than 2,880 channels of data), and the following positive observations were made:

1. There were **observable changes** in the data collected with the Blumio sensor **that corresponded to BP changes measured via our tonometer**; and
2. There were clinically observable differences between subjects, which means it was theoretically possible to differentiate the blood pressure characteristics of each subject.

The Macquarie University trial compared Blumio’s radar sensor with a radial tonometer, which is the non-invasive gold standard in measuring arterial pressure waveforms at the wrist. The resulting paper was accepted and presented at IEEE’s Body Sensor Conference in May 2019 (as announced to the ASX). This was a critical step towards commercializing Blumio’s sensor technology, as it allowed Blumio to showcase its innovation to the main industry body in the field of physiological sensing.

In the paper, Blumio demonstrated that the pulse pressure waveform from Blumio’s radar sensor contains features expected from a cardiovascular signal and is similar to a tonometer. However, unlike a tonometer, Blumio’s sensor does not touch or apply pressure to the measurement site. A number of medical devices, including the Sphygmocor XCEL from CardieX, use the tonometer to acquire a cardiovascular signal, which effectively means that it is possible to integrate Blumio’s sensor into those devices as a replacement for the tonometer to provide a non-invasive blood pressure monitoring solution in a clinical setting.

Commenting on the Blumio sensor, **Professor Alberto Avolio from the Faculty of Medicine and Health Sciences at Macquarie University recently stated:**

*"The Blumio sensor uses radar technology in combination with sophisticated signal processing and is able to detect the waveform of the blood pressure pulse from very small variations of the skin surface over an artery, typically the radial artery at the wrist. It is able to track changes in blood pressure and pulse waveform that occur with physiological tests such as the Valsalva manoeuvre. An important distinguishing feature of the Blumio sensor is that it is essentially contactless, and as such increases the potential applications of this type of sensor".*

These initial results provided sufficient validation for us to move to the next phase under the JDA.

### **JDA Stage 2 – Refinement and Development of Signal Processing Algorithms - Completed**

I am pleased to announce that CardieX and Blumio teams have now successfully achieved the JDA Stage 2 milestones in algorithm development since completion of JDA Stage 1 discussed above:

1. CardieX has successfully developed an algorithm to process Blumio's sensor signals (select the channel) and produce reliable cBP waveform and parameters. This means that the Blumio wearable sensor can potentially replace a tonometer in one of our existing devices or any other device that uses a tonometer for BP readings; and
2. CardieX has successfully identified the method to calibrate the Blumio signals with one-time off cuff BP measurement. This means that continuous BP/cBP and their variability can be measured with the Blumio sensor – the first time this has ever been achieved.

This is a technologically significant and commercially material milestone for CardieX as a company.

### **Next Steps and Milestones for JDA**

The next steps going forward under the JDA involve the following:

1. Blumio continuing sensor development efforts and producing a refined Development Board; and
2. CardieX developing the "Desktop Demo App" to display BP/cBP as well as central pressure waveform and associated parameters using the CardieX developed and owned algorithm.

Specifically, Blumio is improving its sensor and radar frequency algorithm to provide a stable and simplified output to the CardieX algorithms set, while CardieX focuses on collecting and analysing Blumio's output. Our aim is to further isolate this data and subsequently track its changes as BP/cBP varies, which is a prerequisite for the completion of the above goals and the development of a reference design for commercialization in late 2019/early 2020.

## Final Comments

The objective of our initial investment in Blumio was to obtain a seat at the table in a significant growth market that directly impacts the future of heart health management for billions of people globally. By combining our teams, both Blumio and CardieX are now substantially more than the sum of our individual parts as we collaboratively work to solve one of the biggest outstanding challenges in health and medical technology.

Our R&D, trials, JDA, and other activities with Blumio are driving towards one ultimate goal – to prove out the equivalency and fidelity of signals from a wearable and non-invasive BP/cBP sensor, which we can jointly exploit in one of the biggest commercial opportunities in the medical device sector.

We are solving some big population problems and developing technologies that can have a positive impact on global healthcare markets as we continue to increase shareholder value.

Thank you as always for your support,

**Craig Cooper**  
CEO

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### CardieX, Limited

CardieX Limited 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. CardieX also has a joint venture partnership with Blumio, Inc in Silicon Valley for the development of a radar-based blood pressure sensor incorporating CardieX technology. In November 2018 CardieX entered into an agreement with Telehealth services provider, inHealth Medical Services, Inc, allowing CardieX to acquire up to 50.5% of inHealth by way of a convertible note.