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CardieX Announces Partnership with Andon for Manufacture of Next Generation Telehealth and Remote Patient Home Health Monitoring Devices

Highlights:

- Three-year co-development and commercial partnership agreement announced with one of China's largest manufacturers of home-use medical electronic devices
- Partnership to initially focus on World's first cloud-connected home-use BP monitor device to include ATCOR's patented SphygmoCor® technology and Arty™, ATCOR's new cardiovascular vital signs and telehealth platform
- First home device, ATCOR "Pulse", targeted for commercialization in USA, Europe, Australia and China in Q4 2021
- ATCOR "Pulse" will be the first new medical device for ATCOR since 2012
- ATCOR "Pulse" device significantly expands commercial market opportunity for CardieX into the home consumer health and remote patient monitoring markets, both large multi-billion dollar markets

CardieX Limited (ASX: CDX) (CardieX, the Company) is pleased to announce that CardieX subsidiary ATCOR has entered a co-development and commercial partnership agreement (the Agreement) with Shenzen Stock Exchange listed company, Andon (<u>002432.SZ</u>), one of China's largest manufacturers of home-use medical electronic devices.

The Beginning of a New Generation of ATCOR Medical Devices

The three-year co-development and commercialization agreement with Andon provides for the development and commercialization of new medical and consumer health devices for home-use based on ATCOR's patented and global standard SphygmoCor® technology for measuring central blood pressure and arterial stiffness.

The first device under the Agreement to be named ATCOR "Pulse" (the Device) and will be targeted for commercial launch in the US, Europe, Australia and China in Q4 2021.

ATCOR "Pulse" will be the **first new medical device for ATCOR since 2012** and represents a game changing medical technology collaboration for home-use vital signs monitoring. This unique device will be the **world's first cloud-connected home-use BP monitor** to include



ATCOR's SphygmoCor® technology and Arty™, ATCOR's new cardiovascular vital signs and telehealth platform (Arty™ being an anagram of "Heart" and "Artery").

The Agreement with Andon in conjunction with the ATCOR "Pulse" device significantly expands the commercial market opportunity for CardieX into the **home consumer health device market**, which is estimated to be worth \$US2.5B annually (*Source: Fortune Business Insight*).

When paired with ATCOR's Arty[™] app, the Device will provide full remote patient monitoring of a patient's vital signs at home. The **remote patient monitoring market** is estimated to reach \$US43B by 2027 (*Source: 2020 Research & Markets Report*).

At launch, the device and will also be fully telehealth-enabled with video, chat, messaging, customizable screens and full vital signs sharing features between clinician and patient when paired with the Company's Arty™ app. ATCOR Pulse will be the first blood pressure device ever to feature customizable screens and vital signs modules when integrated with the Company's new Arty™ app.

Material Terms of the Agreement

The key terms of the agreement are:

- The agreement is between Andon Health Co. Ltd and 100% CardieX Limited wholly owned subsidiary, ATCOR Medical Pty Ltd;
- Intellectual property ownership is explicitly retained by ATCOR as the sole and exclusive owner of all intellectual property rights related to ATCOR technology and ATCOR BPM;
- ATCOR has the sole exclusive right to distribute the product in ANY territory;
- The agreement has a term of three (3) years and can be extended or renewed upon the written agreement of both parties;
- Terms of payment by ATCOR to Andon are generally based around milestones of the
 product development and FDA clearance and this will revert on completion of the FDA
 clearance to a per unit payment to Andon to produce product for ATCOR's inventory
 and sales distribution. The total budgeted development costs are material however
 each milestone payment individually is not material in the company's opinion material;
- ATCOR will sell and supply to Andon its CBP Chip that will be used as part of the production process of the new ATCOR Pulse device.



Regulatory Pathway for Full FDA Approval on Release of New Products

Under the Agreement, Andon will be responsible for obtaining regulatory approvals in all target markets. Regulatory approvals will initially be required for the USA, Australia, China and Europe.

ATCOR's SphygmoCor® technology is already approved in all of those markets as is Andon's blood pressure module which will be incorporated into ATCOR "Pulse". ATCOR already has multiple integrations and approvals of its SphygmoCor® technology in other FDA, European CE, Australian and Chinese NMPA approved devices.

The regulatory pathway for submission of a final FDA approval is truncated for companies such as ATCOR and Andon who have existing FDA approved devices in market and the Company expects this to be the case here.

Upon receiving US regulatory approvals, ATCOR "Pulse" will also provide access to a CPT reimbursement code through Medicare and Medicaid allowing physicians to receive reimbursement for remote patient monitoring of central blood pressure and other parameters via the new device.

Security of Intellectual Property and 100% Distribution Rights

Importantly, under the Agreement, ATCOR will remain the sole and exclusive owner of IP rights to central blood pressure monitoring as well as having sole distribution rights in all territories worldwide. Andon will purchase ATCOR's SphygmoCor® chips to integrate into the ATCOR "Pulse".

The intention for the Device will be to target multiple new channels and markets including hypertension, cardiovascular health, vascular dementia and Alzheimer's, as well as other health disorders.

Bringing ATCOR Technology from the Pharma and into the Home

Hypertension and cardiovascular disease are the world's #1 killers with 18 million deaths a year. Measuring arterial stiffness is considered to be one of the best predictors of risk for hypertension and cardiovascular disease. Lancet and WHO have each called for more precise measurements of risk for cardiovascular disease using arterial stiffness, which is not available on standard blood pressure monitors.

ATCOR's SphygmoCor® technology is the global standard for the non-invasive measurement of arterial stiffness in medical settings with all "Top 20 USA Hospitals" using ATCOR's SphygmoCor® technology, over 4500 installations worldwide, and used by major pharmaceutical companies and research institutions such as The Mayo Clinic, GlaxoSmithKline, AstraZeneca, Bayer, Scripps, Johns Hopkins, and Stanford University.



Over 1,600+ papers have been published on ATCOR's technology in leading peer-reviewed journals like *Hypertension*, *Journal of Clinical Hypertension*, and the *Journal of the American College of Cardiology*.

ATCOR "Pulse" will serve as the hub for the Company's home health-tech strategy and strongly positions the Company in three of the largest growing health-tech market segments:

- Home vital signs and remote patient monitoring (combined market value US\$43B by 2027 - Research & Markets Report);
- Telehealth for cardiovascular and other vascular health disorders via the embedded telehealth functionality in our Arty™ app (telehealth market projected to reach US\$55.6B by 2025 – Markets&Markets 2020 Report); and
- **Digital health** via the Company's Arty™ digital health platform (a US\$509B market opportunity by 2025 Grand View Research).

ATCOR "Pulse" is part of an ecosystem of new devices and products in development by the Company in home health, digital health, clinician vital-signs monitors, wearables, and smart devices − which will all connect in to our Arty™ digital health ecosystem, thereby creating a unique digital platform for monitoring consumer health and vital signs.

Bringing the Future of Medical Diagnosis into the Home – Telehealth Ready

Aside from measuring conventional blood pressure parameters, "ATCOR Pulse" also introduces central blood pressure, advanced beat-to-beat heart rate measurement (HR+™), Arterial Stiffness Factor™, Arterial Age™, Heart Stress™, Vitals Risk Score™, Exercise Capacity™ (eCAP), and the Arty™ score – features never before available on a home blood pressure or vital signs device.

These trademarked algorithms have all been specifically developed based on the Company's core SphygmoCor® technology and represent a unique selling proposition when incorporated in all of ATCOR's new devices.

ATCOR "Pulse" will also integrate with ATCOR's companion smartphone app (Arty™ GO), a proprietary cloud infrastructure (Arty™ Cloud), and the multi-platform physician portal (ArtyNet™) for a comprehensive heart health management ecosystem that launches ATCOR into telehealth and remote patient monitoring, two healthcare frontiers experiencing significant growth.

In the Company's opinion this also represents the first significant step in bringing Arty™, ATCOR's digital health platform, into the homes of millions of consumers across the world for advanced cardiovascular health management focused on central blood pressure and arterial stiffness monitoring.



Craig Cooper, CEO & Managing Director of CardieX commented:

"This is the most significant announcement of the Company's evolution since I became CEO and represents a major value milestone for all shareholders.

We now have the foundations of a fully developed ecosystem of home-health devices, digital health & telehealth solutions, wearable partnerships, and a remote patient monitoring platform - each of which target significant health-tech market opportunities - and each based on our patented SphygmoCor® technology.

Going forward we will continue to expand our product portfolio with new devices including new partnerships in medical and clinician based vital signs monitoring, wearables, and other health technologies".

Mr Wang Yong, Vice President at Andon commented:

"We are very excited to partner with ATCOR to develop the world's first cloudconnected home-use blood pressure monitor with central blood pressure measurement capabilities.

In the face of current healthcare needs, this kind of next-generation technology for more personalized cardiovascular health management is even more necessary".

Authorised for release by the full Board of Directors, and released by Jarrod White

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About Andon

Tianjin Jiu An Medical Electronics Co., Ltd., also known as Andon Health, is one of the largest home-use healthcare electronics manufacturers in China, specializing in R&D, production and commercialization of home healthcare products as well as health management cloud platform and services. Listed on the Shenzhen Stock Exchange (002432.SZ) with a current market cap of approximately RMB 5.3B (AUD\$1B), Andon's principal business operations are in Tianjin, China, with subsidiaries in Silicon Valley (iHealth), Paris (eDevice), Beijing, as well as Singapore.

In 2010, Andon introduced the world's first mobile and connected BP monitor, which was subsequently added to Apple's official online and offline sales channels. Since then, a wide portfolio of personal health and wearable devices have been developed by Andon, including blood glucometers, pulse oximetry, ECG, heart rate monitors, weight scales, body composition scales, sleep trackers and other devices. With the 2014 iHealth JV in collaboration with Chinese smartphone giant Xiaomi as well as the 2016 acquisition of Paris-based eDevice, Andon is hailed as a pioneer and front runner in the global mobile health industry

For more information, please visit https://jiuan.com/

About CardieX

CardieX is a global health technology company that focuses on hypertension, cardiovascular disease, and other vascular health disorders. The company's ATCOR division is the world leader in medical devices for measuring arterial stiffness and central blood pressure waveforms based on its unique FDA-cleared and patented SphygmoCor® technology. Under the ATCOR.X brand, the company also develops and licenses its Arty™ platform consisting of physiological and health analytics for wearable devices. The company's digital platform, ArtyNet™, is a connected SaaS ecosystem providing physicians with a complete telehealth solution for remotely managing patients' health (2021 launch).