



ASX Announcement

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China FDA Approval Achieved for Oscar 2 Blood Pressure Monitor with CardieX's "SphygmoCor® Inside" Technology

Highlights

- China FDA (CFDA) approval for Oscar 2 with "SphygmoCor® Inside" received; a market leading Ambulatory Blood Pressure Monitor (ABPM) for use in China for monitoring of central blood pressure.
- Total addressable new CardieX revenue and market opportunity for sales of Oscar 2 with SphygmoCor® in China of approximately \$USD50 million per annum.
- Oscar 2 with SphygmoCor® is a successful existing collaboration between leading US based blood pressure monitor manufacturer and distribution company SunTech Medical, and CardieX wholly owned group company AtCor Medical.
- Oscar 2 is a state-of-the-art ABPM featuring integration of AtCor's advanced SphygmoCor® technology measuring central aortic blood pressure, including aortic blood pressure determination and central pressure waveform analysis.
- The Oscar 2 allows for highly accurate blood pressure data to be collected from a patient over a 24-hour period outside of a physician clinic or hospital environment and features patented cuff design for patient comfort, as well as advanced motion tolerance algorithms.
- CardieX's SphygmoCor® technology is the global gold standard in central blood pressure and arterial stiffness assessment, with over 1400 published studies and 4000+ global deployments.
- Oscar 2 with SphygmoCor® will be the only available ABPM solution in China currently with "SphygmoCor inside" and provides a unique market differentiation for ABPM devices in this significant medical device segment.
- Hypertension is a significant and growing market in China. ABPM data is collected by physicians and used to analyse blood pressure data for early diagnosis and treatment.
- CardieX and SunTech will both share in total Oscar 2 with SphygmoCor® sales revenues via product margin splits.
- CFDA approval in China will expand on the existing collaboration between SunTech and CardieX for sales and distribution of Oscar 2 with SphygmoCor®. The device is already FDA approved for sale in the USA and is CE marked for sale in the European Economic Area.

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- **Anticipated new shared revenue stream from sales of Oscar 2 units with SphygmoCor® in China to commence in the second half of 2019.**
- **CardieX and SunTech's Oscar 2 collaboration is a prime example of CardieX's strategy to drive growth through partnering with established major market players globally via licensing and integration of CardieX's proprietary IP and technology across a broad range of digital and device based global health solutions.**

CardieX Limited (ASX: CDX) (CardieX, the Company) is pleased to announce approval by the Chinese Food and Drug Administration (CFDA) of the Oscar 2 with "*SphygmoCor® Inside*" Ambulatory Blood Pressure Monitor (ABPM), a product collaboration between CardieX wholly owned group company AtCor Medical (AtCor) and leading US blood pressure device manufacturer SunTech Medical Inc.

The Oscar 2 device features integrated SphygmoCor® technology supplied by CardieX's subsidiary AtCor and is manufactured by SunTech Medical, which is based in North Carolina with sales offices in Europe and China. The companies share sales margins on a defined ratio that is a function, in part, of which company is the selling party.

Approval by the CFDA will allow the Oscar 2 ABPM with SphygmoCor® to be utilised by over 20,000 physicians, hospitals and clinics throughout China where ABPM is the most effective method of detection, diagnosis, monitoring and management of hypertension - a leading cause of more than 12% of annual adult deaths worldwide. Hypertension is a major and growing health disorder in China with over half the adult population currently affected.

With a growing preference for in-home monitoring and management, Oscar 2 with SphygmoCor® allows for patients to monitor blood pressure over a 24-hour period in their own homes and away from physician clinics and hospitals – a need that is specifically important in the Chinese market where the medical infrastructure and overburdened hospital systems often lead to less than optimal treatment and diagnosis.

CardieX believes the total addressable market opportunity for sales of the Oscar 2 with SphygmoCor® in China alone is approximately \$USD50 million. With a combined sales effort between SunTech and AtCor China sales divisions we believe a 10% market share is potentially achievable. This potential is enhanced by the unique and proprietary nature of CardieX's SphygmoCor® technology that is not currently available in any other Chinese ABPM device.

As part of a global market strategy CardieX is also seeking to create additional OEM partnerships with dominant market players in China for in-hospital vital sign monitoring, home-use blood pressure monitoring, digital health solutions, and smart wearables.

Leveraging the immense channels developed by domestic Chinese manufacturers, CardieX is rapidly accelerating its internal vision of implementing central blood pressure and related health technology solutions in the largest population market on the planet.



CardieX CEO, Craig Cooper commented:

“Achievement of CFDA approval for Oscar 2 with SphygmoCor® marks yet another significant milestone for CardieX and is an excellent example of our global health strategy in action. This collaboration which combines our gold standard SphygmoCor® technology with the specialised blood pressure device manufacturing and distribution network of SunTech Medical highlights the way CardieX aims to develop, grow, and expand into the largest and most significant health market in the world.

The Chinese market for hypertension is massive and growing at over 6% per annum and there is an enormous need for effective blood pressure monitoring tools to meet the requirements of physicians, clinics, and patients. Oscar 2 with SphygmoCor® will add a new and important revenue stream to our business going forward which will be further supplemented by our other Chinese initiatives and partnerships currently in process.”

For more information please contact:

NWR Communications

Peter Taylor or Anne Leslie

peter@nwrcommunications.com.au

anne@nwrcommunications.com.au

CardieX

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 with SphygmoCor® 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 and has a majority interest* in leading telehealth company inHealth Medical, Inc with partnerships with Anthem, Blue Cross Blue Shield, and American Well.

*Pursuant to a Convertible Note

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