



ASX ANNOUNCEMENT

14 April 2022

CardieX announces FDA 510(k) submission for CONNEQT Companion App to New Dual Blood Pressure Monitor

Highlights:

- **CardieX consumer health subsidiary, CONNEQT, has submitted a US FDA 510(k) clearance application for the CONNEQT App.**
- **The CONNEQT App is a companion application for the CONNEQT Pulse device which, subject to FDA-clearance, will be the world's first home-use dual blood pressure (BP) management system incorporating CardieX subsidiary ATCOR's SphygmoCor[®] technology.**

CardieX Limited (ASX:CDX) (**CardieX, the Company**) is pleased to announce that it has submitted a 510(k) clearance application to the US Food and Drug Administration (FDA) for the CONNEQT Companion App (App), a smartphone application with the ability to integrate with the CONNEQT Pulse device (Pulse), a new dual blood pressure monitor, which is in the final stages of regulatory documentation prior to FDA lodgement.

CONNEQT App

The CONNEQT App is part of a new digital ecosystem for both consumers and clinicians all based on CardieX subsidiary, ATCOR's existing FDA-cleared SphygmoCor[®] technology. The CONNEQT App will integrate with the CONNEQT Pulse device, a new home-based heart health vital signs monitoring system, that measures central blood pressure, arterial waveforms, and multiple other arterial health parameters based on the existing FDA-cleared SphygmoCor[®] technology used in the Company's other devices.

Once the Pulse device and App are connected, patients will have access to and be able to manage, a complete suite of arterial diagnostics. It will also incorporate health coaching, patient record sharing, and remote patient monitoring features for future clinical use.

The Company has completed all of its requirements for FDA submission of the Pulse device and this has been provided to the Company's manufacturing partner, Andon, who are responsible (as manufacturer) for FDA lodgment, which is expected in the short term.

The CONNEQT App forms the hub of CONNEQT's device ecosystem, and will also have the ability in the future to pair with the CONNEQT Band, a smart wearable also featuring a range of patented health and wellness features focused on heart and arterial health, including a



blood pressure monitoring PPG sensor powered by ATCOR's SphygmoCor[®] technology. Significant progress continues to be made on the CONNEQT Band development in concert with Fenda Technology and LifeQ (refer ASX 29 October 2021).

CardieX Group CEO, Craig Cooper, commented:

"This application is an exciting milestone for us as a company as we look back on our 20 years of FDA clearances dating back to our first device clearance in 2002.

Our strategy and vision with CONNEQT has always been to bring medical grade diagnostics to the consumer and it's for that reason that we are seeking FDA clearance for the CONNEQT App – unlike other health apps that are not paired to a medical device ecosystem.

We strongly feel that this will be a unique and significant competitive advantage for us on launch."

Approved by the Board of Directors and Released by Jarrod White, Director.

For more information, please contact:

Investor Relations

Rod Hinchcliffe

rod.hinchcliffe@mcpartners.com.au

Media Relations

Melissa Hamilton

melissa.hamilton@mcpartners.com.au

Investor Relations – USA

Matt Selinger

Managing Director

Integrus Communications

mselinger@integcom.com

About CardieX

CardieX is a global health technology company. Its ACTOR subsidiary is a world leader in medical devices and digital solutions for hypertension, cardiovascular disease, and other vascular health disorders. Its CONNEQT subsidiary develops and markets consumer home health devices and wearables. CardieX is listed on the Australian Stock Exchange (ASX:CDX).