23 June 2026 **ASX ANNOUNCEMENT**

CONNEQT Lodges FDA Pre-Submission for SphygmoCor Cloud

Highlights:

- SphygmoCor Cloud package lodged under the FDA's Q-Submission programme, to commence the pathway to 510(k) clearance as a Software as a Medical Device (SaMD).
- SphygmoCor Cloud transitions CONNEQT's clinically validated arterial health analytics from dedicated hardware to a cloud-based SaMD platform, supporting broader market access.
- Creates the potential for new commercial pathways: Biomarker-as-a-Service (BaaS), third-party device integration, enterprise licensing, and direct-to-consumer digital health applications.
- SphygmoCor's clinically unique arterial health biomarkers are supported by 50 years of foundational research, 24 years of FDA-cleared clinical deployment and thousands of peer-reviewed publications.
- If cleared, SphygmoCor Cloud would represent CONNEQT's sixth FDA-cleared product.
- FDA written feedback anticipated August 2026; 510(k) submission targeted Q2 FY27; potential FDA clearance targeted Q3-Q4 FY27.

CONNEQT Health Limited (ASX: CQT) ("CONNEQT" or "the Company") is pleased to announce the lodgement of an FDA Pre-Submission package for SphygmoCor Cloud, the Company's next-generation Software as a Medical Device (SaMD) platform.

Evolution of SphygmoCor – from hardware to cloud

Built on more than 50 years of foundational research pioneered by our founder, Dr. Michael O'Rourke, and commercially deployed since receiving its first FDA clearance in 2002, SphygmoCor technology has been the global gold standard for non-invasive assessment of arterial stiffness and central cardiovascular health. Trusted by leading research institutions, hospitals, and clinical programs across more than 40 countries, the SphygmoCor technology and devices have generated an unmatched body of clinical evidence, underpinning thousands of peer-reviewed studies and forming the backbone of cardiovascular risk research globally.

Until now, access to the full clinical analytics platform required dedicated hardware in a professional setting. By migrating CONNEQT's validated cardiovascular analytics engine into a cloud-based SaMD architecture (SphygmoCor Cloud), the Company proposes to deliver the same clinically credentialed

assessment through compatible devices, applications, and digital health platforms with significantly reduced deployment complexity.

What SphygmoCor Cloud Enables

The strategic importance of moving from a hardware product to a cloud-based SaMD platform fundamentally enhances how CONNEQT creates and captures value.

Biomarker-as-a-Service (BaaS)

SphygmoCor Cloud creates the infrastructure for CONNEQT to offer its arterial health biomarker engine as a licensed service, enabling third-party medtech companies, consumer device manufacturers, and digital health platforms to integrate SphygmoCor-validated analytics directly into their own products. This enables partners to access SphygmoCor Cloud's analytical layer and deliver clinically actionable cardiovascular risk data.

Third-Party Device Integration

SphygmoCor Cloud, via API's, is designed to support integration with compatible device companies, medical-grade peripherals, and consumer health technology. By enabling SphygmoCor analytics to be accessed by a broad range of compatible devices, the addressable market expands well beyond CONNEQT's hardware footprint.

Enterprise and Population Health Licensing

Health systems, insurers, and large employer health programs may in future access SphygmoCor Cloud as a licensed platform, enabling cardiovascular risk screening and monitoring without deploying CONNEQT hardware.

Consumer and Direct-to-Patient Channels

SphygmoCor Cloud provides the opportunity to unlock further distribution through consumer-facing channels, including app-based delivery, telehealth integration, and subscription-based cardiovascular monitoring services.

A Scalable, Recurring Revenue Model

This transition drives the ongoing shift from one-time device sales to software licensing and subscription revenue, creating the potential for higher margins, greater predictability, and a compounding of the installed base over time.

A Platform Foundation for Future CONNEQT Products

SphygmoCor Cloud is designed to be the analytics foundation across CONNEQT's entire product ecosystem. All next-generation CONNEQT products will be SphygmoCor Cloud enabled, ensuring that as the platform scales, every new product generation inherits the full power of the cloud analytics engine.

Competitive Position: A Clinically Distinct SaMD

CONNEQT's competitive advantage is founded on 50 years of foundational research and the extensive clinical validation of SphygmoCor technology, which has been deployed through FDA-cleared products for more than two decades and underpins thousands of peer-reviewed publications.

If cleared, SphygmoCor Cloud would be CONNEQT's 6th FDA clearance. This would further enhance the Company's position as a global leader in clinically validated arterial stiffness and cardiovascular risk assessment.

Regulatory Pathway

The Company has lodged an FDA Pre-Submission (Pre-Sub) package under the FDA's Q-Submission programme, a formal mechanism through which the FDA provides written feedback on key aspects of a proposed regulatory strategy prior to a full 510(k) application. This is a strategically important step: it allows CONNEQT's regulatory, engineering, clinical, and quality teams to address potential questions before submission, improving the efficiency of the clearance process.

During the Pre-Sub review period, the Company will continue preparing the full 510(k) submission package, including technical documentation, validation evidence, and supporting regulatory materials. Following receipt of FDA feedback and the Pre-Sub meeting, CONNEQT intends to incorporate any recommendations and proceed with the formal 510(k) submission.

SaMD 510(k) clearances for cardiovascular analytics are an established and growing regulatory category. As of 2025, 97% of AI-enabled and software-based medical devices have been cleared via the

510(k) pathway, with cardiology representing one of the fastest-growing segments. CONNEQT's extensive clinical evidence base and the well-characterised predicate landscape for arterial health analytics strengthens the regulatory foundation for this submission.

Regulatory Timeline

Milestone	Target Timing*
FDA Pre-Submission lodged	June 2026
FDA written feedback received	August 2026
FDA Pre-Submission meeting	Late August / Early September 2026
FDA 510(k) submission	Q2 FY27
Targeted FDA clearance	Q3–Q4 FY27

*Timing is indicative only and subject to FDA review processes, feedback, requests for additional information and other factors outside the Company's control.

Craig Cooper, CEO, CONNEQT Health:

"This is a significant step forward for CONNEQT, not just the filing, but the opportunity it opens up.

SphygmoCor is built on more than 50 years of foundational science and 24 years of FDA-cleared clinical deployment, but to date, that body of evidence has been locked inside a hardware device. Moving to SphygmoCor Cloud and Software as a Medical Device (SaMD) means the same validated cardiovascular intelligence that has underpinned thousands of peer-reviewed studies may in the future be deployed at scale through third-party devices, apps, health systems, and consumer platforms anywhere in the world.

Though our devices remain central to what we do, SphygmoCor Cloud adds a second engine to the business, one that can scale independently of hardware and reach a market opportunity substantially larger than our devices alone can access.

We believe SphygmoCor Cloud has the potential to expand our global reach, enable capital efficient scaling of the business and enhance our competitive position."

Approved by the Board of Directors and Released by the Company Secretary

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For more information, please contact:

Investor Relations
Rod Hinchcliffe
rod.hinchcliffe@mcpartners.com.au

Media Relations
Melissa Hamilton
melissa.hamilton@mcpartners.com.au

About CONNEQT HEALTH

CONNEQT Health's mission is to increase longevity through medical technology advancements in vascular health. The Company's suite of products includes medical and home health devices and digital solutions for hypertension, cardiovascular disease, and other vascular health disorders - all based on the Company's market-leading SphygmoCor® vascular biomarker technology. CONNEQT Health is listed on the Australian Stock Exchange ("ASX: CQT").