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ASX Announcement

Control Bionics enters strategic joint venture with NextLevel Assistive Technology to expand iOS speech-generating device platform in the United States

Control Bionics Limited (ASX: CBL) (“Control Bionics” or “the Company”) is pleased to announce that its US subsidiary, Control Bionics Inc. (“CBI”), has entered into an exclusive manufacturing, distribution and intellectual property licence agreement with NextLevel Assistive Technology (“NextLevel”) to jointly commercialise a new range of iOS-based speech generating devices (“SGDs”) in the United States.

The partnership will enable Control Bionics to expand its presence in the large and growing US Augmentative and Assistive (‘AAC’) market through a capital-light, distributor led model aligned with the Company’s existing strategy.

Key Highlights

- Exclusive agreement with NextLevel to manufacture, distribute and sell UnoTouch Omni and Active (Apple) iOS-based SGDs in the United States
- Control Bionics to act as FDA Manufacturer of Record and distributor through established partner channels
- NextLevel to fund all device tooling and manufacturing
- Control Bionics to receive a fixed per device contribution margin
- Control Bionics is currently in advanced negotiations with multiple US distributors under non-binding Letters of Intent
- This is a capital light structure, with positive working capital dynamics

Strategic Rationale

The partnership combines NextLevel’s Apple iOS tablet-based SGD designs with Control Bionics’ regulatory standing, production capability and established US distribution network.

Under the agreement:

- NextLevel designs and manufactures device chassis and components
- Control Bionics performs final assembly, regulatory compliance and distribution
- Devices are marketed under the UnoTouch Omni and Active product lines

US iOS Speech-Generating Device Market Opportunity

The United States is the largest global AAC market, with an estimated 2.5–3.5 million individuals with complex communication needs requiring speech-generating solutions.

Within AAC, there has been a structural shift toward tablet-based SGDs, particularly iOS-based devices, driven by:

- familiarity of consumer tablet interfaces
- broad AAC software ecosystem
- lower hardware costs
- reimbursement coverage under Medicare and private insurers

Industry estimates indicate:

- ~60–70% of new US SGD prescriptions are now tablet-based
- Annual US SGD unit volumes of approximately 55,000–65,000 devices
- iOS-based SGDs representing a US\$100–150 million annual segment

The NextLevel partnership positions Control Bionics to participate directly in this high-volume segment, complementing its higher-complexity NeuroNode platform.

Control Bionics is currently **in advanced negotiations with multiple US distributors** under non-binding Letters of Intent.

These arrangements contemplate potential annual volumes in the range of approximately 1,000 - 1,500 iOS devices, subject to execution of definitive agreements, regulatory and reimbursement processes, and market rollout.

There is no certainty that these negotiations will result in binding agreements or that contemplated volumes will be realised.

Alignment with Distributor-Led Strategy

The partnership expands Control Bionics' addressable AAC segment through its established US distributor network while maintaining focus on neural interface innovation.

Control Bionics CEO Jeremy Steele said:

“This partnership allows Control Bionics to participate at scale in the largest segment of the US AAC market through our existing distributor channels, without capital investment or manufacturing risk. It is revenue, profit and cashflow accretive.

It complements our NeuroNode neural-interface platform by adding a high volume iOS device portfolio, strengthening our position as a leading AAC technology supplier to distribution partners across the United States.”

About Next Level Assistive Technology

NextLevel is a US-based developer of speech-generating device hardware designs focused on iOS-based AAC solutions. Under the agreement, NextLevel retains ownership of device intellectual property and funds manufacturing of chassis components supplied to Control Bionics for final assembly and distribution.

This ASX announcement has been approved for release by the CEO of Control Bionics Limited.

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For further information visit the website: <https://www.controlbionics.com/>

About Control Bionics:

Control Bionics is a Neurotechnology medical device company that has more than 20 years' experience in the development and use of surface Electromyography (EMG) devices.

About NeuroNode:

Our core patented NeuroNode technology is a wireless wearable device that detects minute signals sent from the brain to any skeletal muscle and is captured as EMG output. This output is then sent wirelessly via the NeuroNode to a personal computer, enabling speech and other computer-controlled functions like email and texting. Our technology is integrated with eye gaze technology whereby the eye gaze enables a cursor to be moved about a computer screen, driven much like a mouse, and the NeuroNode acts as like the mouse button. Control Bionics is the only such product to harness three modalities – touch, eye and NeuroNode control – which combined yield unique benefits in terms of the ability of patients to express themselves with significantly faster speed and less fatigue.

About NeuroStrip:

Control Bionics is currently commercialising its most recent advancement in its technology, the NeuroStrip. This wearable, miniaturised EMG device provides the business with the opportunity to enter new markets such as health diagnostics, sports performance and rehabilitation to name only a few potential markets.

Control Bionics operates in North America, Australia, Europe and Japan.

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