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Control Bionics signs German distribution agreement with Tobii Dynavox for the NeuroNode

Highlights

- Control Bionics has signed a distribution agreement with Tobii Dynavox GmbH for distribution of the NeuroNode® in Germany.
- The NeuroNode is listed in the German Medical Aids Directory (Hilfsmittelverzeichnis, or HMV) under Position Number 16.99.04.1013, issued by the GKV-Spitzenverband, and is reimbursable under German statutory health insurance.
- Germany is one of the largest augmentative and alternative communication (AAC) markets globally and among the largest in Europe.
- Training of Tobii Dynavox's German sales organisation has commenced, with the first regional team trained and the balance to be scheduled progressively.
- The partnership launches today at Rehacare, in Duesseldorf, the largest Assistive Technology Conference in Europe.
- The agreement is non-exclusive, has an initial term of 12 months, and contains no minimum purchase or minimum revenue commitment.

Control Bionics Limited (ASX: CBL) (Control Bionics or the Company) advises that it has entered into a distribution agreement with Tobii Dynavox GmbH for the distribution of the NeuroNode in Germany.

Tobii Dynavox is one of the world's largest providers of assistive communication technology. Its German business operates regional sales teams across the country and holds established relationships with the clinicians, therapy centres and schools through which assistive communication devices are prescribed and supplied in that market.

The NeuroNode is a wireless, wearable sensor that detects the small electrical signals generated when a user attempts a muscle movement, together with spatial movement, and converts them into a reliable switch input. It allows a person with severe motor impairment to operate a speech-generating device, computer or tablet, and is frequently used alongside an eye-gaze system where the user retains only minimal voluntary movement. The NeuroNode is CE marked under the European Medical Device Regulation and holds clearances in the United States and Australia.

Why the HMV listing matters

As announced in March, NeuroNode has been included in the German Medical Aids Directory (Hilfsmittelverzeichnis, HMV) issued by the GKV-Spitzenverband, the peak body of Germany's statutory health insurers, under Position Number 16.99.04.1013.

Inclusion in the HMV requires a device to demonstrate its function, safety and clinical benefit to the satisfaction of the GKV-Spitzenverband. It is an independent validation of the technology and, importantly, it establishes a defined funding pathway for German clients: a clinician prescribes the device, the client undertakes a trial, a funding application is made to the client's Krankenkasse, and the device is supplied through a service provider. Without an HMV listing, each case must be argued individually and the prospect of reimbursement is materially lower.

Market opportunity

Germany is one of the largest markets globally for AAC devices and the largest in Europe, supported by a universal statutory health insurance system and an established network of specialist assistive technology providers. The combination of an HMV listing, a funded pathway to the end user and a distribution partner with national reach is the basis on which the Company has prioritised Germany within its international expansion.

Rollout and next steps

Tobii Dynavox's German business operates through regional sales teams. The first of these has completed NeuroNode training, and training for the remaining regions is being scheduled progressively. Control Bionics is providing trial and demonstration stock, product and clinical training, and German-language software and documentation to support the rollout.

Both parties will attend RehaCare in Düsseldorf from 23 to 26 September 2026, where the NeuroNode will be shown to the German AAC community alongside Tobii Dynavox's extensive range of AAC technology.

The agreement is non-exclusive and has an initial term of 12 months, renewing automatically unless either party gives notice. Revenue under the agreement will depend on the pace at which Tobii Dynavox's sales consultants are trained and build their pipelines, and on the timing of individual funding approvals by Krankenkassen, which are assessed case by case and can take several months to resolve. The Company is accordingly not in a position to forecast revenue from the German market at this time, and will update the market as sales volumes develop.

Commentary

Jeremy Steele, CEO and Managing Director of Control Bionics, said:

“Germany has been a deliberate focus for us since the NeuroNode was listed in the HMV earlier this year. That listing was the hard part. It validates the technology against an independent standard, and it means a German clinician can prescribe the NeuroNode knowing there is a funded route for their client. What we needed next was reach, and Tobii Dynavox gives us that. It is the same wholesale model we are executing in the United States — putting the device in the hands of partners who are already in front of the clinician at the point of assessment. We are realistic about the pace. Reimbursement decisions in Germany take time, and we would rather let the volumes speak for themselves.”

Lars Mutio, Managing Director of Tobii Dynavox Germany, said:

“We see the NeuroNode as a genuine addition to what we can offer clients here rather than a substitute for anything we already sell. For clients whose eye control is deteriorating, or who cannot sustain a mechanical switch, it extends the point at which they can keep communicating independently. Our team in Cologne has had the device in their hands and the response has been very positive. With the HMV listing in place we can take it to clinicians with a clear funding pathway, and we look forward to introducing it more widely at RehaCare.”

This announcement has been authorised for release by the Board of Control Bionics Limited.

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About Control Bionics

Control Bionics Limited is a neurotechnology company commercialising objective, non-invasive neural-signal technology proven in clinical environments and built to scale across multiple markets. Its neural-signal platform captures the body's physiological signals, including the electrical activity generated by muscles, with medical-grade precision and converts them into measurable, decision-ready outcomes. A single underlying technology platform serves four applications: Performance, Rehabilitation, Research & Data, and Assistive Communication. The technology has historically been deployed in assistive communication and is now being extended into sports performance, rehabilitation, medical research, platform partnerships and broader human-computer interface applications. Control Bionics' technology does not require surgery or implantation, and holds regulatory clearances in the US, Australia and Europe. The Company is also a registered NDIS provider in Australia.