



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Control Bionics

By TIM BOREHAM

ASX code: CBL

Share price: 5.8 cents

Shares on issue: 445,317,670

Market cap: \$25.8 million

Chief executive officer: Jeremy Steele

Board: Stephen Rix (chair), Mr Steele, Damian Lismore, Prof Robert Heard, Prof Nicholas Opie

Financials (Year to June 30, 2026): receipts \$5.3 million, net cash outflows \$5.7 million, June 30, 2026 cash \$2.1 million (ahead of \$7.25 million from second tranche of capital raising)

Major shareholders: Nightingale Partners 19.2%, Phoenix Development Fund 16.5%, Reitham Equity GmbH 13.89%

With a background in investment banking, Control Bionics CEO Jeremy Steele appreciates the commercial realities of gaining a foothold in the US medical device market.

That is: it's not easy.

Initially, the company took a direct-to-retail, do-it-yourself (DIY) approach with its assistive communication tool, Neuronode.

Based on surface electro-myography (EMG), Neuronodes are watch-sized, wireless, neuro-electric sensor enabling people with disabilities to use their own 'brain-to-muscle' electrical signals to control communication and movement.

"When I joined the company three and a bit years ago it was a retail business," Mr Steele says. "We were packaging up technology and selling it effectively directly to the end consumer."

The business grew to a handy \$6 million a year turnover – slightly more than the company's run rate for the 2025-'26 year. But the "market realities" became apparent, he says.

"Particularly in the US, you rely on the insurance regime to be able to make the business work. It was clear to me it was going to be very difficult for us to scale without investing enormous amounts of money."

The solution?

Control Bionics has opted to sell through large, specialist partners with a streamlined route through often byzantine insurance payment channels.

At the start of the year the company signed up its two biggest partners: Tobii Dynavox and PRC-Salttillo. With a combined salesforce of 250 people, these parties specialize in assistive communications products.

"Not only do we have the advantage of the scale of their sales reps, but their in-network contracts mean they get paid more quickly - and they sell more," Mr Steele says.

Off its own bat, the company might have to wait one to three months - or even longer - to get paid.

In the meantime, Control Bionics has found a bigger opportunity for a product variant called Neurostrip, for the sports performance and rehabilitation sectors (see below).

Neurostrips measure physiological data such as unintentional muscle movements.

What a good idea

Based in Melbourne's technology hub of Cremorne (near Richmond), Control Bionics was founded in 2005 by Queenslander Peter Ford, a computer scientist and technology broadcaster on the US network CNN.

In 2014, Control Bionomics acquired Therapeutic Alliances of the US, which owned key patents over electro-myography monitors. Backed by local 'angel' investors, the company listed on the ASX in December 2020, having raised \$15 million at 60 cents apiece.

A former marketer, Rob Wong joined as CEO in January 2017 but resigned in September 2022, owing to poor health.

He was replaced by Mr Steele, who has expertise in the healthcare, software, financial services and retail sectors.

The US Food and Drug Administration approved Neuronode in 2020.

In December 2024, the company attained crucial US Healthcare Common Procedure Coding System (HCPCS) coverage.

The reimbursement code - E2513 if you must know - locks in a rate of \$US4,300 (\$A5,988) per device.

This month, the FDA registered and listed the Neurostrip platform as a medical device.

Strictly speaking, Control Bionics doesn't need this imprimatur for the sports and rehab markets, but it helps with the street cred.

Neuronode explained

Electro-myography (EMG) is about capturing and processing neuro-electric signals into electronic commands. The technology enables a person to control a cursor with their eyes and then select an item from where the cursor lands.

Neuronode involves 'tapping' the neural (or visual) signals, as sent from the brain to the muscles.

A finger movement happens because the brain sends a signal that hits a muscle. The muscles don't have to be functioning; as long as the electrical signals exist.

Users include those with motor neuron disease, spinal cord injuries, cerebral palsy and multiple sclerosis.

Neuronode uses algorithms to convert the body's neuro-electric signals into code, which controls the devices. The algorithms are the company's 'secret sauce'.

Other rival assistive technology devices require a keyboard, mouse, joystick, touch screen or eye-tracking to function.

Neuronode3 combines Neuronode with speech-generating software, while Neuronode Trilogy combines Neuronode with eye-tracking technology.

The device attaches anywhere on the body where the user has intentional control.

For instance, a person with deteriorating motor neuron disease might start with the device on their wrist, then a toe or even an eyebrow.

Neurostrip explained

A miniaturized version of Neuronode, Neurostrips measure physiological data such as unintentional muscle movements.

While based on the same technology, Neurostrip is a “very different business” to Neuronode.

Apart from targeting different markets, Neurostrip is sold on a software-as-a-service basis.

“Importantly it generates a lot of data that can be used by existing customers and for future third-party uses,” Mr Steele says.

Locally, Control Bionics has signed up the Australian Football League clubs Greater Western Sydney - a foundation customer - and Hawthorn.

The company has National Rugby League clubs Brisbane Broncos on its books, as well as Australian Rugby and the Australian Institute of Sport.

“The clients are using the tech in different ways,” Mr Steele says.

These customers pay a fee to buy the equipment and then a software fee. Varying between \$US3,500 (\$A4,872) a year and “north of \$US20,000”, the cost depends on how the clients use the devices and how many devices they adopt.

The biggest Neurostrip customer to date, Ohio University, has about 30 devices and might end with 100 units.

Local use tends to be about injury management, while in the US it’s more about performance (for example, establishing a baseline level of muscle activation).

“The beauty is that once the technology is in there, the club can use it for whatever they want,” Mr Steele says.

Go to rehab? Yes, yes, yes

While Australians and Americans love to talk about sport, on pure numbers the rehabilitation opportunities for Neuronode are more significant than the athletic side.

In the US, the company has signed about half a dozen rehabilitation groups and has started rolling out Neurostrip in the UK.

Demand has exceeded management’s expectations.

The company believes about 50 percent of rehabilitation patients could benefit from surface electro-myography (EMG).

Physiotherapist practices are another potentially fertile source of custom, given pain and muscle movement measures can be highly subjective.

Mr Steele says the science of surface EMG does not need to be proven in a rehabilitation context.

“We're not [presenting] some new-fangled technology. Plenty of clinical research has been done over years and years.”

However, physiotherapists haven't embraced EMG because it has not been efficient or effective enough.

A physiotherapy session might last half an hour, so if the device takes 15 minutes to attach, the clinician won't use it.

“Our system can be attached to the skin in about three minutes.”

Germany beckons

Neuronode devices are approved in the US, European Union, Canada, Australia and – as of this week - the UK.

Outside the US, Control Bionics is focused on entering Germany, the world's second largest assistive communications market by value.

The company should announce its first German distributor imminently, with a launch “in the coming weeks”.

Neuronodes have been listed on Germany's Statutory Health Insurance Medical Aids Directory. This confers reimbursement similar to HCPCS in the US.

“It's a compelling opportunity,” Mr Steele says. “But we will need to work with our German partners to develop demand.”

The company is also tackling Japan, where the products don't need to be approved.

She'll be Apples

Control Bionics also is selling products called Next Level; with Apple Ipads infused with the company's technology.

Apple has conferred the company has the exclusive rights to the devices, which are compatible with Apple's new Brain-Computer Interface (BCI) and Human Interface Device (HID) protocols.

Mr Steele says Neuronode suits complex conditions such as motor neuron disease.

“It is low volume, high value market”.

Users don't have the ability to touch a screen.

Then there's a separate market for children with autism and other special needs.

“These children are using devices to communicate by touching with their fingers, rather than using Neuronode [and eye gaze technology] to connect to it.”

In the US, about one million such devices are sold each year.

“We were approached by one of our existing customers who was looking to change from their existing supplier and wanted to work with us instead,” Mr Steele says.

“We partnered and got access to, or licenced, some innovate designs.”

Control Bionics has signed a letter of intent with an unnamed customer, who has paid a \$US100,000 deposit for 1,000 devices over 12 months.

The tablets cost around \$US3,000 each, wholesale.

The company is pursuing US Medicare approval for the tablets.

Mr Steele describes Next Level as a “margin opportunity” the company will confine to the US market.

Once the Next Levels are launched in the current quarter, they should generate “meaningful revenue” as Neurostrip turnover builds more slowly.

Finances and performance

Control Bionics reported June (fourth) quarter receipts of \$1 million, taking the 2025-26 financial year tally to \$5.28 million.

This largely reflected Neuronode sales, with about 80 percent of revenue deriving from the US.

Mr Steele says the flat quarterly number partly reflected the company's transition from a retail to wholesale model.

“We've scaled back retail as we build wholesale, but the timing [of revenue] hasn't matched exactly as we had hoped.”

He says management expects “material revenue growth” in the current financial year. In June, for the first time, monthly wholesale revenue exceeded retail turnover.

The company reported June quarter net cash outflows of \$1.6 million, with a full-year deficit of \$5.7 million.

In June, the company announced a \$9.5 million placement, in two tranches of \$2.25 million and \$7.25 million.

Shareholders approved the latter at a meeting this month, while the company also raised \$250,000 in a share purchase plan.

The raising was done at 7.5 cents per share, a 14.5 percent discount.

Over the last year Control Bionomics shares have vacillated between 3.2 cents (late October last year) and 9.3 cents (early June this year).

The stock peaked at \$1.24 on listing day.

Can someone clean up the NDIS-mess?

Control Bionics' local prospects have been held back by ongoing problems with accessing National Disability Insurance Scheme (NDIS) funding for Neuronode.

About 90 percent of local Neuronode sales are NDIS funded and the company has \$1.1 million of customer receipts awaiting approval or submission.

The Federal Government is determined to rein-in the ballooning cost of the NDIS – and the company appears to be a victim.

Dr Boreham's diagnosis:

Mr Steele says he knows that Neurostrip is hitting the spot because athletes have asked how they can buy the company's shares.

"These are people who understand the importance of being able to improve their performance," he says.

On the sporting side, if anything, the company is competing with other non-electro-myography wearables that assess performance.

With Neuronode, Mr Steele says the new distributors are "finding ways to engage with clients they've not been able to [access] before, because our technology is unique and we are the only ones with an HCPCS code."

But an "impatient" Mr Steele rues the Neuronode rollout is "just not going fast enough".

"The reality is that by definition the industry has long sales cycles," he says.

"We're dealing with individuals with compromised needs; that means they can't do everything as quickly as you'd like them to."

“We also deal with an insurance regime that is slow to move.”

Impatient shareholders may have heard it before, but the next 12 or so shape up as a seminal period as the company’s US distributor sales ramp up.

Then there’s Neurostrip, which is likely to be a bigger opportunity than Neuronode.

The company cites a \$US1 billion market size for the Neuronodes. The Neurostrip lands at \$US2 billion for sport and \$US2.2 billion for rehabilitation.

“The demand clearly is there,” Mr Steele says.

“As we build demand, people will come to us”.

Dr Boreham is not a qualified medical practitioner. He does not possess a doctorate of any sort because he was too impatient to stay the course; and the demand wasn’t sufficient.