



## CAPITAL STRUCTURE

### Current

SHARES ON ISSUE	199.3m
MARKET CAP	\$8.57m @ 4.3c
CASH (30/5/24)	\$2.05m
UNDILUTED EV*	\$6.52m

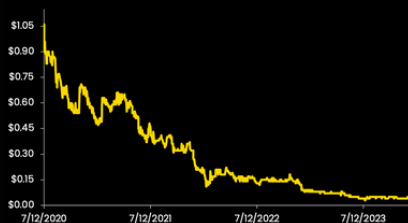
\* Nil debt

### Unlisted Options

DIRECTOR OPTIONS	4.4m
BROKER OPTIONS**	2.0m

\*\* Lynx Advisors holds 1m 10c options exp 2 years and 1m 15c options exp 2 years.

## SHARE PRICE SINCE IPO



## TOP SHAREHOLDERS

PHOENIX DEVELOPMENT	18.3%
NIGHTINGALE PARTNERS	12.5%
PETER SHANN FORD	11.5%

## DCF VALUATION

19c

## ADVISORS

Joe Durak  
+61 414 465 582

Kanak Sahasrabudhe  
+61 406 133 864

Joe Vescio  
+61 478 786 553

## LYNX ADVISORS

1300 871 766  
ACN 654 471 262  
CAR 1293460 | AFSL 456663  
www.lynxadvisors.com.au



## CONTROL BIONICS (ASX:CBL)

Control Bionics Limited (ASX: CBL) is an Australian medical device company specialising in innovative electromyography (EMG) solutions for assistive communication, mobility, and data measurement. Since its IPO in December 2020, the company has prioritised expanding its core business, which continues to grow organically. However, recent innovations have opened new avenues for growth.

With its extensive experience in commercialisation, patented world-class technology, and regulatory approvals across multiple jurisdictions, including the US, CBL is primed for expanded global reach. Bolstered by a strong pipeline of new products and diverse growth prospects, Lynx Advisors views CBL as an attractive investment opportunity.

## 01 INVESTMENT HIGHLIGHTS

- Global business with low EV of \$6.5m compared to peers. FY23 revenues of \$6.1m. FY24 H1 revenues of \$3.5m.
- Currently deeply mispriced, with an intrinsic valuation of \$0.19 compared to a current 4.3c price. It also shows strong relative value against ASX-listed peers, with an estimated value of \$0.21.
- High barriers to entry with best-in-class, regulatory approved and proprietary IP-backed technology in US, AU, UK, Japan, and Europe.
- Scalable and diversified next-generation solutions, servicing a global market and in many cases, with little or no competition.
- Many levers for growth with new products, uses, markets, and channel partners.
- Near-term cash-flow breakeven before corporate overheads.
- CBL's new NeuroStrip data measurement product has endless use-cases across multiple demographics and clinical contexts which will deliver recurring revenue.
- Early entrant with a proven, tested and well regarded product across multiple jurisdictions.
- Highly accessible for consumers through multiple rebate schemes on a global level.
- Experienced management team with previous medical technology experience.

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# 1 Initially inspired to help people like Stephen Hawking communicate

CBL's journey began in 2005 when Peter Ford founded the company with the vision of revolutionising assistive technology for individuals with disabilities and disease. The company received early investment from the Phoenix Development Fund, and Stephen Hawking trialled the concept for many years, with his input shaping the company's journey.



Click to watch this video about the company and Peter Ford's vision.

The initial focus was on developing the NeuroSwitch, a ground breaking device that allowed users to control computers using subtle muscle movements. The company merged this technology with its own speech generating software, creating a wireless and wearable Augmentative and Alternative Communication (AAC) device aimed at improving or substituting conventional communication methods for people facing challenges in speech or language. Specifically, EMG technology uniquely facilitates communication and environmental control for individuals with limited motor abilities.

AAC products are:

- Augmentative when used to supplement existing speech.
- Alternative when used in place of speech that is absent.

With James Schorey as the Chief Technology Officer, CBL has **continuously improved the company's core technology**, making it **smaller, lighter, and more versatile** over time. This means the company can **now offer new solutions beyond its core AAC disability market**.



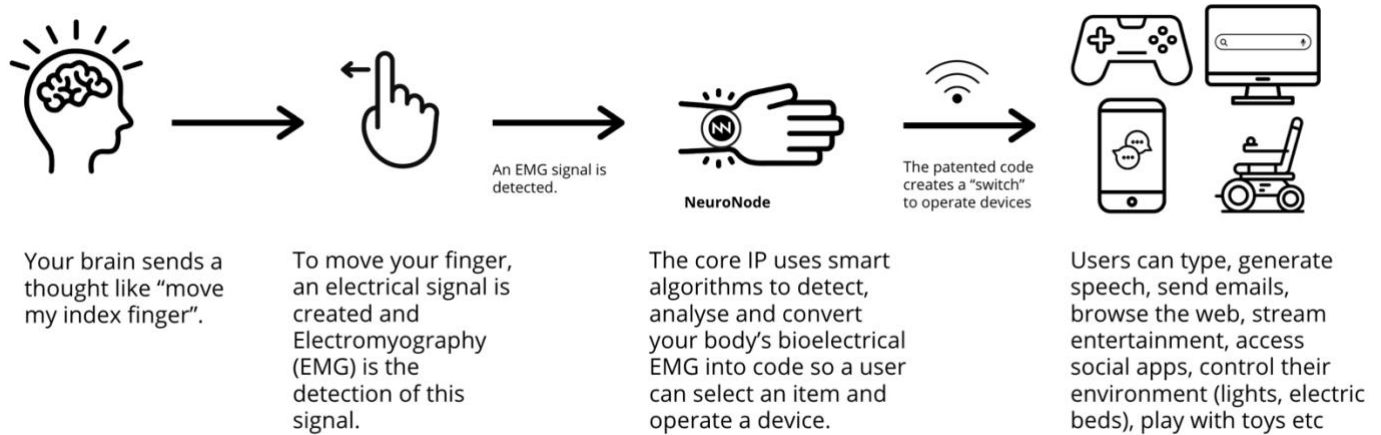
One of the first prototype systems in the NeuroEDUCATOR series was developed 20 years ago with feedback from Stephen Hawking who trialled CBL's technology for many years.

A wireless, wearable NeuroNode was first launched in 2017. Using their IP, EMG assists disabled people in accessing technology for the world's best communication experience.

Just launched in 2023, the NeuroStrip is a miniature version of CBL's core IP. It propels the company into data measurement, a key lever for growth with unlimited uses beyond disability.

## 2 EMG Innovation: The key differentiator for CBL’s solutions

Control Bionics' **key competitive edge revolves around EMG**, a technique that detects and interprets electrical signals generated by muscle activity. By harnessing these signals, the company's patented algorithms translate bioelectrical EMG into actionable commands, or a “switch”.



As per the diagram above, the company's flagship product, the NeuroNode, enables users to type, speak, and navigate digital interfaces using EMG signals. While the new NeuroStrips can perform the same function more accurately, they offer new physiological data measurement capabilities in a compact, wearable form and were specifically designed for uses beyond the disability market.

## 3 Product Portfolio

The company's product portfolio is evolving from primarily serving disabled individuals to **now entering new untapped markets** such as medicine, sports science, and rehabilitation.

	CUSTOMERS	CURRENT CORE PRODUCTS	NEW PRODUCTS
<p><b>ASSISTIVE COMMUNICATIONS</b></p>	<p>Disabled and diseased people with degenerative neurological conditions, spinal cord injuries, cerebral palsy, and other conditions with movement restrictions.</p>	<p>Speech-generating solutions with flexible access methods (touch, eye, EMG) to assist people with various conditions. NeuroNode bundles give the world's easiest and fastest communication experience with the least effort.</p>	<p>Standalone EMG and spatial access method that can connect to competitor products for the best available communication experience.</p>
<p><b>ASSISTIVE MOBILITY</b></p>	<p>Disabled and diseased people who have powered wheelchairs. This population size is larger than the assistive communication market.</p>		<p>A world-first allowing powered wheelchair users to safely and independently navigate their home.</p>
<p><b>DATA MEASUREMENT</b></p>	<p>Endless market and application possibilities outside of the disability market like medicine, sports science and rehabilitation.</p>		<p>A world-first all-in-one accelerometer and EMG device that measures physiological data like unintentional muscle movement.</p> <p><b>NEUROSTRIP</b></p>



### 3.1 Existing Assistive Communication Products

#### 3.1.1 Customer types and technology access

Control Bionics **primarily serves two customer groups** with assistive communications: individuals with **Cerebral Palsy** and those with Amyotrophic Lateral Sclerosis (**ALS**), a form of Motor Neurone Disease (MND). These two segments **contribute equally to 50% of the company's sales** in Australia and the US.



Click to watch this video about how CBL's solutions help their users

In the case of cerebral palsy, people typically have uncontrollable movement which may pose challenges for competitor assistive communication technologies.

Research studies from the American ALS Association show about 80% of individuals with ALS experience mobility impairments due to muscle weakness and paralysis, which can progress over time.

About 80-95% of people with ALS also cannot meet their daily communication needs using natural speech as their disease progresses. About 25% of people with cerebral palsy cannot speak.

Spinal Muscular Atrophy (SMA), Spinal Cord Injury, brain injury, stroke and other neurodegenerative diseases account for the remaining 50% of Control Bionics' sales.

A key Control Bionics' advantage is its ability to integrate its patented EMG solution with third-party technologies, providing customised solutions for its customers. It does this by **offering three flexible communication and speech-generating access options** as per below:



##### TOUCH ACCESS

For those who can touch a computer screen to select letters, words, phrases, or symbols to learn language or communicate.



##### EYE ACCESS

EyeGaze is our state-of-the-art eye tracking system enabling those who can only move their eyes to control a computer mouse. The highly accurate camera with learning algorithm and software determines what button the user is looking at and, if they hold their gaze long enough, the device selects it. For both in and outdoor use.



##### EMG AND SPATIAL ACCESS

Only possible with our patented NeuroNode. It's a wireless, non-invasive EMG and spatial sensor that communicates with a display device via Bluetooth, acting as a bridge between a person's thoughts and technology. This is the world's fastest access method.

connects →

##### Our key communication device and software



A computer to generate speech, browse the web, listen to music, and more. Other devices like smartphones, Xbox, robotics, and electric beds can also be connected to our system.

#### 3.1.2 NeuroNode: Core innovation and CBL's best competitive edge

CBL's core IP is embodied in the NeuroNode, a watch-sized, wearable, wireless, internet-enabled, programmable neuroelectric sensor.

It's the only solution globally to combine EMG and spatial sensors. This allows it to detect both intentional muscle movements (EMG) and intentional gestures (spatial). This makes it particularly useful

for cerebral palsy users, where involuntary movement is misinterpreted by other assistive technology, leading to much frustration and greater communication abandonment.



NeuroNode can detect signals even without visible muscle movement, a crucial feature for ALS patients to maintain reliable communication as their condition worsens.

CBL also has a provisional patent for AI-based software, which turns their core technology into a game. This allows users to make their own digital art and stories to share with teachers, parents, and loved ones. The company thinks this is first of its kind.

### 3.1.3 NeuroNode Trilogy: The ultimate in communication



The NeuroNode Trilogy, introduced in 2022, integrates touch and eye control with the NeuroNode sensor, significantly enhancing accessibility and communication speed for users. Along with decreasing tiredness, studies show this technology package increases communication speed up to 47% compared to stand alone traditional eye tracking methods.

This 3 in 1 solution suits those living with paralysis and loss of speech. **Unlike other technologies, no movement is required to communicate.**

### 3.1.4 Communication product suite overview

CBL's entry-level product is the UnoTouch. Its flagship product, the NeuroNode Trilogy, offers three communication access methods for the market's fastest, least tiring, and easiest experience.

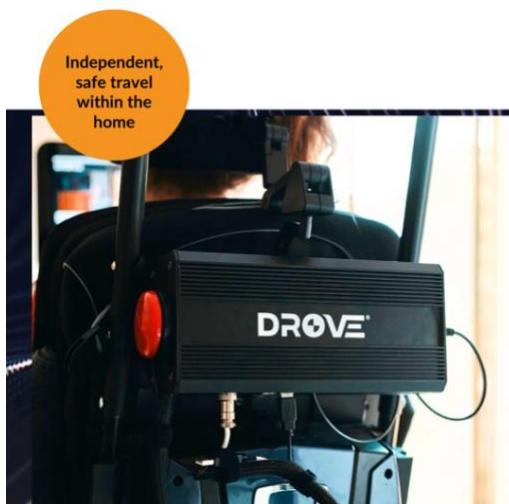
	UNOTOUCH	EYEGAZE	NEURONODE	NEURONODE	COSMOS
	Bundle with a NeuroNode for faster, less tiring and easier communication				
<b>USER TYPES</b> A user's condition will determine the type of access method and hence product	Entry level access for those who can touch a screen to communicate	Entry level for those who can only move their eyes to communicate	A UnoTouch upgrade with EMG access for greater efficiency	Includes all 3 access types for ultimate efficiency or high physical incapacity	
<b>PRICING (SAUD FOR AUSTRALIAN USERS)</b> Rental with buyout option starting price Buyout option starting price	\$1,000 \$3,200	\$3,800 \$9,000	\$5,400 \$16,875	\$8,000 \$20,875	n/a \$950
<b>SPEECH GENERATING COMPUTER &amp; SOFTWARE</b> Powerful, professional-grade system including language software for use on the go	✓	✓	✓	✓	
<b>EYE TRACKING TECHNOLOGY</b> Controls a computer mouse with your eyes using a camera and continuous learning algorithm	✗	✓	✗	✓	
<b>NEURONODE SENSOR</b> EMG signal and spatial control gives users flexibility to change access modes	✗	✗	✓	✓	
					Access smart phones, play video games, activate switch toys, dine independently, and more

### 3.1.5 CBL’s key points of differentiation

Overall, CBL’s combination of advanced and patented technology, user-friendly design, and personalised support gives it a **distinct competitive edge in the assistive communication market.**

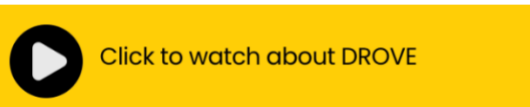
Other Providers	Control Bionics	Benefit to the customer
Require a keyboard, mouse, joystick, touchscreen, or eye tracking to function.	Uses EMG and/or eye tracking.	✓ Proven to be both faster and less fatiguing in multiple studies. It also reduces repetitive strain injuries and gives people who cannot use eye technologies, like those with cerebral palsy, the ability to communicate.
Require movement.	Can detect the intention of movement whilst excluding unintentional movement - patent protected.	✓ Less fatigue, faster, and more consistent communication. Can be used by severely disabled people who cannot move at all.
Single solution offering (eg Tobii or Smart Box).	Offers a choice of speech-generating software, cameras and casings.	✓ Allows customers to make a choice based on the best-suited system for their needs, ensuring effective use and reduced device abandonment.
Only wired or Bluetooth or EMG	Only company to combine spatial, EMG and EOG switch.	✓ Allows flexibility and versatility of use. Caters to a user’s changing needs during the day and as their condition changes over time. Our patent-protected settings ensure a user’s intentions are acted on rather than any unintentional movements.

## 3.2 New Assistive Mobility: DROVE is the world’s first autonomous wheelchair



In 2023, CBL introduced 'DROVE' in partnership with Deakin University’s Applied AI Institute, an autonomous wheelchair system. Whilst it can be used within CBL’s ecosystem, it can also be used independently of CBL’s devices. Essentially an add on module for powered wheelchairs not requiring a joystick or wheel to operate, allowing incapacitated users to navigate their homes independently and safely with reduced cognitive and physical strain.

Recently, CBL received a research grant of USD \$379,492 from the American ALS Association, the largest, national non-profit organisation in the US helping people with ALS. **The research grant will help CBL research the best entry paths into the US.**



There may also be future opportunities to generate revenue by producing de-identified datasets. These datasets could support research on various movement-related diseases.

All products are currently manufactured, assembled, and tested for quality assurance in Australia.




### 3.3 New physiological data monitoring: NeuroStrip is key to growth



In October 2023, Control Bionics launched the NeuroStrip, a smaller and more advanced version of the NeuroNode, marking another milestone in technology innovation and a **crucial step in accelerating CBL's growth trajectory into new markets with seemingly infinite applications** beyond its core business of assistive technology.

The NeuroStrip combines accelerometer and EMG capabilities with spatial data in one device, enhancing the company's ability to collect and analyse data for various new applications. It's features and benefits are highlighted in the table below.

	FEATURE	BENEFIT
	Small, light, flexible and non-invasive. At 3g, it weighs less than a piece of paper and is 4cm long.	Increased choice of placement where you want to switch with, monitor or improve. It's also easy to use.
	With no cables or moving parts, it has unprecedented accuracy (<1 micro volt) with more sensitive readings.	Better uses for medicine, sports science, rehabilitation and other applications yet to be discovered.
	Attaches directly to the skin with no limit to how many are used at any one time.	Increases the number of applications across markets.
	Measures a wide range of electrical signals in the body like EOG, ECG, EMG (and potentially electroencephalography EEG).	Flexibility in choice of signal and ability to measure both intended and unintended movement for a wider range of outcomes.
	Disposable (reusable in final development).	Can be used in medical settings

**Unlike Elon Musk's Neuralink brain chip, NeuroStrip is not implanted in your brain.** Rather, Control Bionics' technology **uses Surface EMG (sEMG)**, where the non-invasive electrodes placed on the skin allow for **measuring five key data points**, offering detailed insights into an individual's **physiology** such as:

1. Muscular activation: Detecting when a muscle is activated.
2. Amplitude of activation: Measuring the strength of muscle activation.
3. Fatigue: Identifying shifts in frequency content during prolonged muscle activation, indicating muscle fatigue.
4. Coordination and timing: Studying biomechanics and movement disorders by analysing EMG across multiple muscles.
5. Comparison between muscles: Comparing muscle activity between different movement disorders.



The **NeuroStrip's non-invasive and disposable design opens potential applications in clinical settings**, including:

1. **Neurological Rehabilitation:** EMG provides feedback on muscle activation patterns, aiding in retraining affected muscles for patients recovering from strokes or other neurological impairments.
2. **Biofeedback Therapy:** Real-time visualisation of muscle activity helps patients learn to control and modulate muscle contractions, beneficial for conditions like chronic pain, muscle spasms, or incontinence.
3. **Orthopaedic and Sports Medicine:** Assessing muscle imbalances or altered activation patterns can identify issues contributing to pain or movement dysfunction.
4. **Assessment of Movement Disorders and Dysphagia:** EMG aids in diagnosing conditions like dystonia, tremors, or spasticity, and assessing muscle activity during swallowing.
5. **Research:** EMG is used in studying muscle function, movement mechanics, and therapeutic interventions across various patient populations.
6. **Prosthetics and Orthotics:** EMG signals control movements in advanced prosthetic limbs, enhancing functionality.
7. **Pelvic Floor Rehabilitation:** EMG biofeedback strengthens pelvic floor muscles, particularly beneficial for urinary incontinence. This requires FDA Class III registration.

While pricing hasn't been set, **management anticipates the disposable version will be sold in higher volumes at a price in the low hundreds of dollars, lowering any pricing barriers**. A reusable version is currently in development and is expected to sell at about double the price.

## 4 Market Analysis

### 4.1 Assistive communication: An underserved niche market with lots of room for growth

According to Research and Market, the Global AAC Devices Market is projected to grow at a CAGR of 11.22% by 2029.

#### 4.1.1 Market drivers, restraints, barriers to entry

##### Drivers

- Increasing prevalence of communication disabilities
- Technological advancements in AAC devices
- Rising awareness and acceptance of AAC devices
- Growing demand for personalised solutions

## Restraints

- High cost associated with AAC devices
- Limited reimbursement policies and coverage
- Lack of awareness amongst healthcare professionals

## High barriers to entry

Entering the EMG market for AAC audiences comes with a swathe of challenges, thus CBL has incredibly high barriers to entry. These include:

- Long lead times for EMG hardware and software to perform its intended purpose.
- Long Lead times for patent approvals in relevant jurisdictions.
- Pre-requisite regulatory healthcare registrations and rebates required for the technology.
- Resources to provide customer services and in-person support for users.
- Partnerships of research and scientific studies

### 4.1.2 Market size

**Each year, about 66,000 new individuals** across the USA, Australia, Japan, UK, and select European nations receive diagnoses aligning with Control Bionics' primary target market as per below. Priced at about A\$20,000, this indicates a minimum **yearly market potential of \$1.3 billion**.

	Australia	USA	Japan	Total	UK	Germany	Belgium	Netherlands	Total UK + Europe	MARKET TOTAL	%
ALS/ MND	400	5,000	2,780	8,180	1,701	2,500	500	500	5,201	13,381	20%
Multiple Sclerosis	520	10,400	300	11,220	-	-	-	-	-	11,220	17%
Cerebral Palsy	440	11,200	2,160	13,800	1,750	1,750	300	400	4,200	18,000	27%
Spinal Cord Injuries	540	17,730	5,080	23,350	-	-	-	-	-	23,350	35%
<b>Total</b>	<b>1,900</b>	<b>44,330</b>	<b>10,320</b>	<b>56,550</b>	<b>3,451</b>	<b>4,250</b>	<b>800</b>	<b>900</b>	<b>9,401</b>	<b>65,951</b>	<b>100%</b>

**Much of this target group also lacks adequate access** to assistive communication devices. For instance, in Germany, 46% of ALS patients need AAC but only 39% receive it. In Scotland, 82.7% of ALS patients don't get AAC devices.

**Focusing solely on existing individuals with cerebral palsy, where CBL's spatial and EMG technology offers a competitive advantage**, the company can target an additional 662,000 individuals across the same markets above excluding the US and Australia. This represents **an additional \$2 billion market opportunity**.

The Steve Gleason Act of 2018 in the United States has become a catalyst for CBL's market, as any eye tracking, gaze interaction accessories, speech generating devices are to be subsidised.

Note that CBL's products could also be used by individuals who fall outside of their target base, with reviews of medical records from the University of Iowa Hospitals & Clinics found that 33% of intensive care unit (ICU) patients met AAC candidacy criterion.

### 4.1.3 Funding: Health insurance rebates are crucial to success

CBL and competitors strategically target geographical markets with extensive health insurance coverage to **offset the substantial costs associated with AAC devices**. This means companies cannot control the approval process nor the amount insurers pay them. However, market experience tends to allow companies to reasonably forecast these reimbursements.

#### US

At least **75% of CBL's sales are through a person's insurance in the US**. Navigating the complex US funding landscape involves targeting regions and funders renowned for robust support to optimise funding opportunities. It's vital to allocate sales resources effectively in these areas to ensure success.

A key advantage for some US competitors is being "in network". This typically means a healthcare provider, such as a hospital, clinic, or service provider, has agreements with various health insurance companies that allow for their customers (patients) to get insurance coverage for services / devices provided by that healthcare operator. This results in easier, faster, lower out-of-pocket costs compared to receiving care from providers outside of their network.

CBL initiated collaboration with a group to help them **get "in network"** last year. With ongoing efforts, the company anticipates that one-third of the 100 insurers it's targeting will onboard within the next year, **helping them achieve their core product growth forecasts**.

Given the intricate reimbursement process in the USA, CBL employs multiple salespeople in that region. The company recognises the onboarding cycle for new sales personnel is lengthy, and success is closely linked to the tenure of its sales team. Longer-serving team members tend to generate higher sales due to the relationship-based nature of the business, and the company incentivises them accordingly.

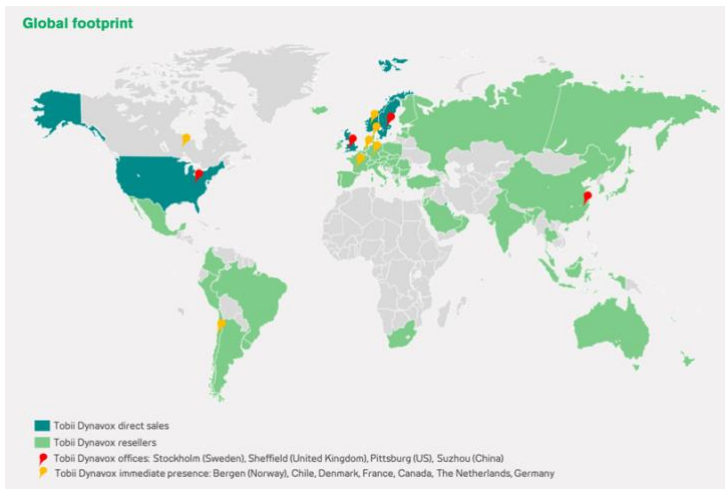
#### Australia

The National Disability Insurance Scheme (**NDIS**) serves as the dominant insurance provider for the assistive technology market, contributing to **87% of Control Bionics' revenue**. Unlike the US, where insurance coverage may only reimburse a portion of the retail price, the NDIS covers 100% of the company's retail price in Australia. While this presents a significant opportunity, reliance solely on the NDIS poses risks, as evidenced by the company's current backlog of approvals.

### 4.1.4 Competitors

#### Non-EMG

**CBL's closest assistive communications competitor in the US is Tobii Dynavox (STO: TVOX)**, a listed CBL company on the Stockholm Exchange with a market capitalisation of A\$870m. Dynavox is a **market leader** with global revenues of A\$225m and EBIT of A\$15m (12% of revenue) in 2023. North America accounts for 78% of revenue under a direct sales model.



The company’s US business grew at a similar rate to CBL during 2022 and 2023, between 22–24%. Key to their US success is being “in network” when it comes to funding, sales and training investment, and acquisitions.

Their own research supports the notion the market is underserved, with a lack of awareness and educating referrers as their biggest challenge.

The company’s products work on a **non-EMG ‘wired switch’ system that requires a ‘tap’ by**

**the user, a less accessible and accurate alternative to CBL’s NeuroNode.** Its solution uses compact modular hardware and software components to deliver eye-tracking software, relying on existing technology that is not proprietary.

It has no competing product with CBL’s NeuroStrip, NeuroNode and DROVE.

**The standalone NeuroNode can connect with Tobii products through Bluetooth and thus, could be viewed as an upgrade on much of their existing product offerings.**

Similarly to Tobii Dynavox, **Smart Box and Prentke Romich Company (PRC)** are targeting the AAC market but do not have any EMG-related products, with a focus strictly on eye tracking, tablet, and software products.

### EMG Technology

**CRTL-Labs (CRTL)** is one of two EMG-focused competitors that CBL is aware of, a private company founded in 2015 predicated on commercialising an EMG wristband capable of transmitting electrical signals from the arm into computer inputs. CRTL was acquired by Facebook in September 2019 for a valuation between US\$500m–\$1bn. CBL is unaware of CRTL pursuing Medicare, Medicaid accreditation or FDA registration for the medical disability market.

**EMEGO** is another competitor with an EMG device, targeting similar use cases as the NeuroNode. While EMEGO’s product is like the NeuroNode, it doesn’t have spatial control, nor does it have the same configurability that is crucial in this market. Like NeuroNode, it has Class I approvals in the UK and can be worn for extended periods of time over a variety of muscles. Trials are continuing to be performed by Barnsley Hospital’s Assistive Technology team with funding from the NHS England and Papworth Hospital NHS Foundation trust. Currently, EMEGO have secured phase II funding and will be testing the device on real patients, with a focus on entry to market.



## 4.2 Assistive mobility: A new market with virtually no competition

The growing prevalence of chronic diseases, neurological disorders, and technological advancements in powered wheelchairs is set to drive industry growth. The trend of rapidly aging demographics like Europe, North America, Japan, and China is further accelerating this growth.

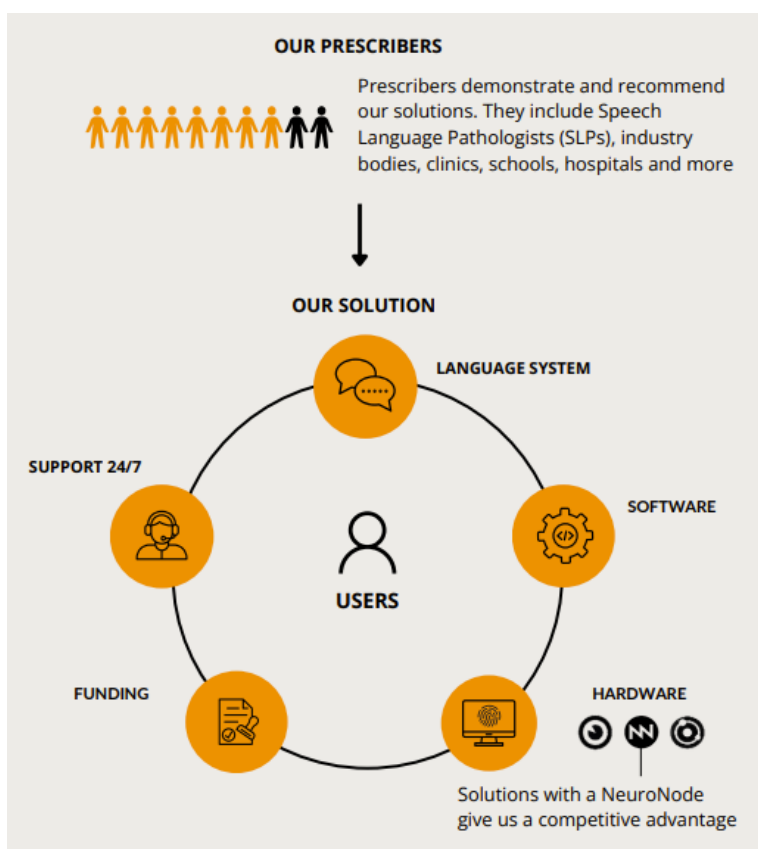
According to Grand View Research, the global powered wheelchair market size is expected to grow at a CAGR of 6.9% from 2024 to 2030.

According to the ALS Association, approximately 5,000 people in the U.S. are diagnosed with ALS each year and about 30,000 are living with the condition. Powered wheelchairs with reclining, two team, and standing functions are essential for patients suffering from this debilitating disease.

There are 2 million new powered wheelchairs sold globally every year, representing a **minimum \$100m market each year for DROVE at a 1% penetration rate.**

There is **further market upside** as CBL could also pursue the existing wheelchair market which is at least 4 times larger as DROVE is an add on product for powered wheelchairs.

## 5 Current retail business model: Selling direct to users



The company sells its assistive communication technology directly to consumers in the USA and Australia, a strategy we anticipate will continue to **drive organic growth.**

CBL relies on both its internal sales team and a network of Speech Language Pathologists (SLPs) in Australia and the U.S. to gain referrals from healthcare professionals and support users in learning how to communicate using their products. By providing free product usage to SLPs and offering training and continued education, CBL can acquire more leads and ensure SLPs are incentivised to recommend their products based on quality rather than price. Additionally, CBL's proprietary EMG technology and competitive advantages position the company favourably for future growth.

## 6 Growth strategy: A new wholesale model | volume selling

A recent pivot towards diversification beyond its core assistive communications market, coupled with a **new wholesale strategy and strategic partnerships, signals a faster path to growth** for the company.

This also includes the introduction of **new products, expansion into new geographic regions and use markets.**

### 6.1 Growth # 1: NeuroNode only - Drive new sales as an accessory

Up to now, the company has mainly offered its NeuroNode devices as part of a package to its retail market. It's **new "NeuroNode only" wholesale strategy involves selling the device as a standalone product** that can be connected to competitor systems as an upgrade or integrated with other assistive technologies. It offers **many benefits** to the company, namely **speed to market, price control and better profitability.**

**Japan is the testing ground for this new strategy** where CBL employs a dual approach to sales. They sell directly to consumers through a small sales team and partner with hospitals, schools, and clinics. These partners can recommend both packaged and unpackaged versions of the NeuroNode to families who buy the product directly. CBL also builds relationships with government bodies and reaches out to potential customers through their social channels to attract leads.

In contrast, in **Europe and the UK, CBL intends to sell its product wholesale** to companies that are already established in the AAC markets for a faster path to market.

The company **doesn't currently offer standalone NeuroNodes in the US** as it is not economically viable given the nuances of the US insurance market. **However, this may change on 1 October 2024** if the company is successful in securing a new code under the Healthcare Common Procedure Coding System (HCPCS). This system is employed by healthcare insurers to standardise the reimbursement process for healthcare and medical products throughout the United States.

**In the Financials Section, we discuss the significance of any approval** because it would allow the company to expedite its US market penetration by selling and revenue sharing its products with competitors who could offer the device as an add-on upgrade to their users.

### 6.2 Growth # 2: DROVE – Deliver first commercial sales

**The company is currently building partnerships with companies that act as distributors for powered wheelchairs** in Australia and the US. The powered wheelchair market in North America dominated the global industry and accounted for a share of 47.8% in 2023 according to Grand View Research. There are several major players such as Invacare, Numotion, Medline, and Carex Health.

### 6.3 Growth # 3: NeuroStrip – Seemingly infinite new markets

**We support the CEO's strategic vision to enter markets with the quickest, lowest-cost access requiring no further regulatory approvals.** The company plans to introduce NeuroStrip to these new

markets through different channels beyond assistive technology to avoid competing with its existing core business.

It's crucial to highlight that **if a NeuroStrip application is solely for data monitoring, additional regulatory approvals are unlikely** to be required. Consequently, regulatory pathways are notably easier, cost-effective, and quicker.

Where applications warrant regulatory approval, CBL will require partners for more research or clinical trials and already have existing relationships with leading researchers.

**While Control Bionics has pinpointed several applications to focus its initial NeuroStrip efforts**, there remain **numerous unknown potential uses**. Additionally, there are niches with unaddressed needs, meaning that CBL won't necessarily face direct competition with existing technologies. In some markets, there are even no competitors or only weak ones.

The company's **initial focus** will be on **sports science and rehabilitation**, areas **where traditional EMG technology is already established**. Control Bionics has existing customers who have purchased legacy systems and are now considering adopting the NeuroStrip, with some already trialling it. CBL is expected to generate income in both markets in FY25.

### 6.3.1 Sports science

Control Bionics is investigating opportunities in the sports industry, with coaches, elite athletes, sports clubs, parents, and children's team sports.

While NeuroStrip has versatile applications, it could, for instance, collect data during movements such as jumping, kicking, and throwing to assess muscle performance and recovery. The goal is to improve athlete effectiveness, prevent injuries, and tailor training plans. Another example is to use CBL's technology to identify children with a natural talent for a particular sport, enabling them to be trained in the right direction.

These initiatives **face no regulatory hurdles**. CBL is in talks with current clients about transitioning to NeuroStrip. For instance, NeuroBounce in the U.S., which offers tailored jump coaching to college athletes using earlier versions of CBL's EMG technology. The company is also pinpointing sports clinics in the U.S. already employing sEMG in their services. It is estimated there are some 100 elite sporting clinics in the US alone.

### 6.3.2 Rehabilitation

Surface EMG is used to assess the level and timing of muscle activation and muscle fatigue to uptrain and down-train muscles.

Discussions are currently ongoing in Australia with BetterRehab, a longstanding advocate and customer of CBL. BetterRehab offers tailored rehabilitation services across 37 locations nationwide to individuals with disabilities. Additionally, CBL is exploring several partnership prospects in Japan.

NeuroStrip **faces minimal regulatory hurdles** for use in rehabilitation, requiring only an engineering change notice to leverage existing approvals.

### 6.3.3 Movement disorders

The next promising market for early entry is neurological movement disorders, where traditional surface EMG is already applied in diagnosing and treating conditions like Parkinson's and Myasthenia Gravis. Current EMG technology for this application is cumbersome, lacks Bluetooth connectivity, and necessitates patients to visit a lab for extended periods. While smart phones and accelerometry watches, such as those from PKG Health, have been available for years, they do not detect EMG.

An EMG solution like NeuroStrip means more accurate data can be obtained from multiple sites on the patient, whether they are at home, in a clinic, or at the hospital. Real-time monitoring of movement tremors could give doctors valuable insights during episodes and treatment, leading to advancements in diagnostic and treatment approaches for movement disorders and neurology.

CBL has partnered with top-tier doctors to outline the minimum viable product (MVP) and is in talks for its implementation. To scale, NeuroStrip will require Class II registration due to its potential for diagnosis and treatment modification. Nonetheless, as surface EMG is already used for similar conditions, and with robust research collaborations, **CBL believes customer trials could start quickly.**

### 6.3.4 Dysphagia

Surface EMG and biofeedback are used to retrain individuals with dysphagia on swallowing, both in clinical settings and at home. CBL plans to reconnect with clinics that have previously expressed interest in their solutions. **Market entry appears feasible as only an engineering change notice is needed** to leverage existing approvals, and developing a specific user interface for this application can be accommodated within existing budgets.

### 6.3.5 Incontinence

Incontinence is also considered a potential early application by the company. While **presenting a significant opportunity**, it would **likely necessitate collaboration with clinical and industry partners for scaling and additional funding for product development.**

The concept involves using NeuroStrip to detect changes in bladder muscle activity before the loss of bladder control. This tool can function as a biofeedback mechanism, assisting individuals in managing their bladder function effectively.

The ideal scenario, requiring further research, involves exploring whether NeuroStrip could activate a neural stimulator to delay bladder outflow until an individual can reach a bathroom. Presently, implanted stimulators fulfill this role, but if a surface EMG strip like NeuroStrip could detect this activity and be applied daily in a non-invasive manner, it could offer a more automated solution, reducing the need for constant manual intervention.



## 7 High barrier to entry: Regulatory approvals in key markets

Control Bionics has secured registrations for various products in multiple countries, including Australia (TGA Class 1), the USA (FDA Class 2), Canada (Ontario Ministry of Health), and Europe (CE Mark) as follows:

	US	Australia	Japan	UK	Europe
Regulatory Scheme	FDA	TGA	PMDA	MHRA	CE Mark
NeuroNode	✓	✓	✓	✓	✓
DROVE	○	○	—	—	—
NeuroStrip *	✓	✓	✓	✓	✓

\* May require further approvals if the product use materially changes

- ✓ Approved
- Pending or near-term application
- Yet to be approved

## 8 Financials

Our financial forecasts indicate that **CBL is deeply undervalued**.

The company is **exploring all avenues to scale and grow**, including distribution channel acquisitions. Its **new wholesale strategy can also substantially increase revenue without adding more fixed costs**, which are expected to remain stable. As a result, incremental revenue from its growth initiatives will primarily boost EBITDA.

**Three key variables excluded from current forecasts that could significantly impact CBL** include:

1. **Approval of a new HCPCS code in the U.S.** On May 6, CBL were notified its HCPCS code application for the US health insurance system had advanced to the final stage of approval scheduled for 28 May 2024. In essence, CBL had applied for a new health insurance billing code for its core product, NeuroNode, as a standalone device in the US.

Up until now, this device could only be bought within a package offered by the company through its retail operations to single end users.

If successful, the company will receive higher reimbursements from health insurers for its NeuroNode Trilogy retail package and will be able to sell to resellers and partners through a new wholesale strategy.

**A verdict will be delivered in August with any changes effective 1 October 2024.**

This promising development could significantly impact the company's business as follows:

- a. Retail business: Will receive an **immediate increase** in the insurance rebate by A\$6500 for the Trilogy retail product, where NeuroNode is included. This **could give CBL a meaningful annual EBITDA boost of some A\$0.8m** given 80% of the 300 units sold in FY23 were in the

US and about 50% were for Trilogy. This is effectively a 32% price increase for the Trilogy package.

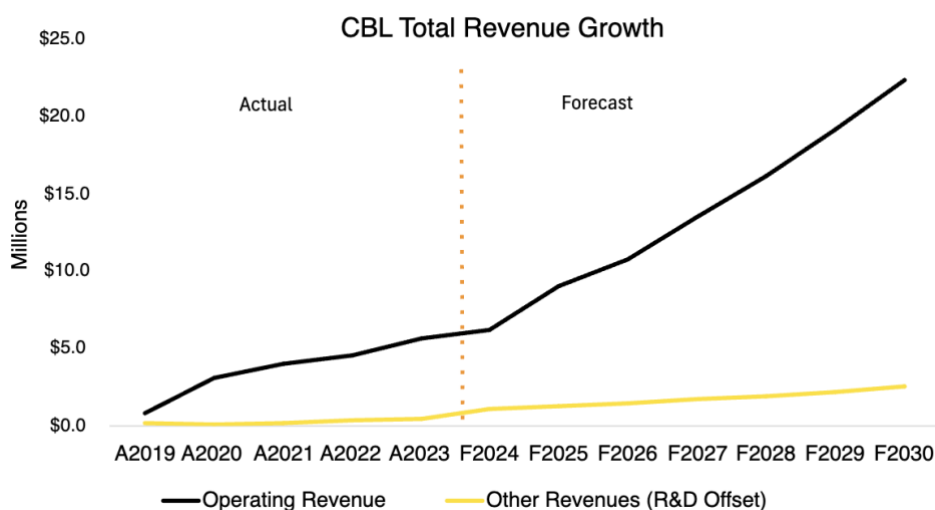
- b. Wholesale business: A new HCPCS code with the proposed price of USD \$4300 makes it viable to revenue share with competitors who can resell a standalone NeuroNode device as an add-on upgrade to existing competitor systems. The benefits to the competitor are a better customer experience, new revenue stream and a major EBIT boost as they are likely to simply incorporate NeuroNode into their existing sales processes. This **could boost CBL's EBITDA by several million** if adopted by the market leader, Tobii Dynavox.
2. Identifying additional NeuroStrip markets with many expecting to **contribute millions in revenue over time**.
  3. Potential **acquisitions**.

## 8.1 Revenues

As of FY24, Control Bionics' revenue primarily comes from its core assistive communication products, with NeuroNode Trilogy as a key revenue driver. **By 2030, we expect a major shift in revenue structure as CBL commercialises new products and adopts a new wholesale strategy.** This approach will boost volume, diversify revenue, and improve working capital by reducing reliance on insurance rebates.

For the 4 years to FY23, CBL's revenue has grown at an average CAGR of 60% to \$6.1m.

We project a total revenue target of \$24.9m for FY2030, including R&D tax offset of \$2.5m. Per GAAP rules, CBL currently categorises its expenditure on R&D activities as income and expects this to more than double from FY22 to FY23 to about \$1.1m as it gets better at capturing R&D expenses.



We expect about a 40% increase in total revenue over the year to FY25 mainly due to:

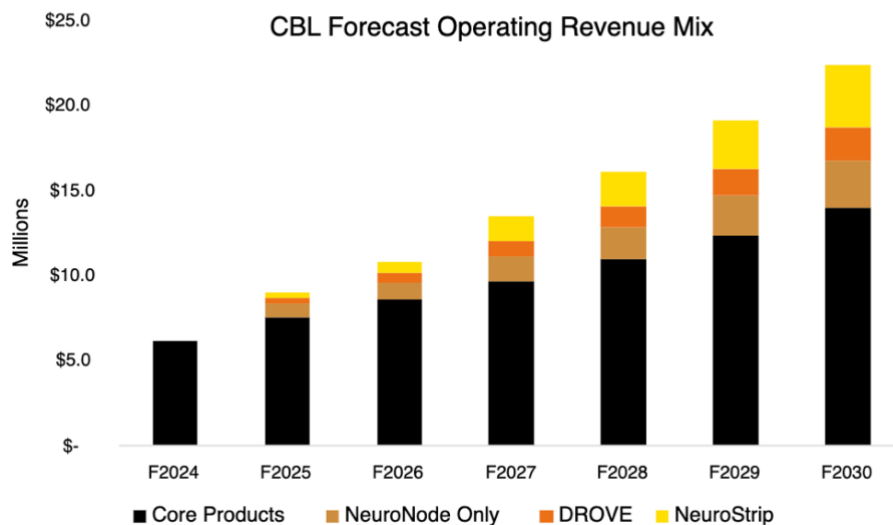
- Conservative 13% organic growth for the core communication business.

- 10% additional growth for the core communication business as we've assumed this amount of revenue is delayed from FY24 to FY25 due to the NDIS application backlog.
- Some \$1.4m new revenue from the start of the company's new wholesale strategy.

Over the last three financial years, CBL's assistive communication business has demonstrated a CAGR of 22%, positively impacted from a backlog of applications from COVID-19 and in line with the market leader's growth over the same period.

Our forecast uses a more conservative CAGR of 13% for this communications business, backed by the company's initiatives to **expand its core U.S. retail business through new distribution partners**. This strategy enables the company to pivot to larger volume sellers who don't rely on traditional insurance funding. Potential partnerships may involve third-party tech companies, state-level school boards, special needs schools, Veteran Affairs (VA), and similar entities.

The company's **new incremental operating revenues are projected to grow at an accelerated pace** over the forecast period and contribute to about 40% of operating revenue by 2030. Revenue from this wholesale strategy is expected to grow from \$1.4m in FY25 to \$8.4m in 2030.



### 8.1.1 NeuroNode only

We expect to see 17 sales per month of the standalone NeuroNode across both Japan, UK, and Europe in 2025. These numbers more than triple by 2030 as the company gains global traction, yielding \$2.8m in revenue in 2030. CBL aims to break even in Japan with just 7 NeuroNodes sold per month which is expected by Dec 2024.

Our forecast is based on the company selling NeuroNode through wholesale channels at USD \$3,000. However, there may also be retail opportunities at USD \$5000 per unit.

Resellers will be key catalysts, reducing the need for higher sales and customer service personnel expenses. The company recently invested in its software and **can scale quickly**.

### 8.1.2 DROVE

DROVE is currently undergoing TGA approval and FDA approval is expected by FY26. Leveraging the CAGR of the powered wheelchair market, we anticipate CBL generating \$2.0 million in revenue from this product by FY30. This projection assumes an 80-20 revenue split between the U.S and Australia, respectively.

It's important to note our forecast excludes the potential penetration into the existing powered wheelchair market which is 4 times larger than the new wheelchairs sold each year. Additionally, there is untapped potential in Europe not considered in the current model.

### 8.1.3 NeuroStrip

For NeuroStrip, **there are a plethora of use cases to be considered for forecasting**. However, our **model focuses primarily on the first four best market entry options currently identified by the company**.

#### 8.1.3.1 Sports science

We've considered just two applications of NeuroStrip in the sports sector, both **limited to specific regions without considering global replication**, and have not included the broader sports market in our forecast.

##### Elite sports clinics (USA)

Our forecast assumptions are based on the experience of CBL's customer, NeuroBounce. They are currently using one of CBL's earlier EMG devices in their program to train athletes' brains, enhancing motor neuron recruitment to the muscles involved in jumping for maximum performance.

Located in Utah, the program annually assists 200 college volleyball and basketball players, helping them secure scholarships. Each participant undergoes EMG assessments four times throughout the training program.

In the US, there are about 25,000 college athletes playing basketball or volleyball across all genders, with about 7,500 new athletes joining each year.

We conservatively forecast \$0.1m in FY25 and \$1.2m revenue in FY30 after growing penetration from 1 to 10 clinics over this period, a 10% penetration of clinics by FY30.

##### Children's sports aptitude (Japan)

Our forecast is based on CBL's current discussions with one Japanese partner who tests children for sports aptitude. Our forecasts include revenue of \$0.4m in FY30 based on the current number of children



seen through their program at an assumed 50% penetration. This penetration could be higher if programs are government funded.

### 8.1.3.2 Rehabilitation

Our model just focused on the Australian hospital market as an example. There are some 24,000 occupational therapists (OTs) and of those, 4,334 work in hospitals. A 20% penetration rate in FY30 yields revenue of some \$0.1m.

There are OTs and physiotherapists (42,000 in Australia alone) who deliver rehabilitation services in both private practice and through hospitals all over the world, so the **market is significantly bigger**.

### 8.1.3.3 Movement disorders

There are some 800,000 people with Parkinson's disease in Australia, the US and U.K with the US accounting for about 60%. We assume first sales in Australia in FY26 followed by US and UK in each of the years thereafter. Market entry is later due to required regulatory approvals in these markets.

Our model assumes a low starting penetration rate of 0.1% with small increases thereafter to yield revenues over \$0.6m by FY2030.

### 8.1.3.4 Dysphagia

The company plans to address the dysphagia market, which government statistics indicate impacts 5.2% of Australians who live in Nursing Homes/Aged Care Hostels and 15-30% of people over the age of 65+. This gives us an addressable market in which 0.7% of Australians have Dysphagia. We assume demographic similarities between Australia, the U.S and the U.K resulting in total addressable market of some 3 million people for these three markets alone.

Our model assumes a low starting penetration rate of 0.1% with small increases thereafter to yield revenues of about \$1.4m in FY2030.

Note that this does not consider individuals in those jurisdictions over the age of 65 with dysphagia who are not in a nursing home. Thus, the **total addressable market could be even bigger** for these markets.

## 8.2 Expenses

CBL's cost of goods has been impacted by higher input prices during COVID over the last couple of financial years and trended at about 35%. Going forward, the **Gross Margin is expected to be about 70%**.

Depreciation and amortisation (D&A) expenses are projected based on historical rates due to the limited growth variability in non-current assets. Selling, general, and administrative (SG&A) expenses are forecast with a 3% growth rate, aligning with the upper end of the RBA's inflation range.

We expect Net Working Capital (NWC) to grow at the same rate as revenue but at a slower pace in later years as the payment cycle shortens with the sale of new products. By diversifying beyond its core retail business, the company can anticipate reducing the payment cycle from 100 days with US health insurance providers.

### 8.3 EBITDA and FFCF

Control Bionics' Australian operations are already breakeven, and management expect their US and Japanese operations to also breakeven by the end of 2024.

The company recognises that growing revenue significantly faster than operating costs is critically important, evidenced by its **continued reduction in EBITDA losses during 1H 2024** relative to the previous half year of some 28%.

The company is **projected to become EBITDA positive in FY27**. This is largely driven by strong increases in incremental revenue from FY25 and FY26 from the introduction of the company's wholesale strategy.

	F2024	F2025	F2026	F2027	F2028	F2029	F2030
EBITDA \$m	-\$3.4	-\$1.4	-\$0.4	\$1.4	\$3.1	\$5.3	\$7.5

CBL is **projected to become free cash flow positive in FY27**. This FFCF value allows us to see how much capital CBL has after paying all costs to run its business. We believe this cash flow is highly reflective of the strong growth in revenues that have been forecast within the model.

	F2024	F2025	F2026	F2027	F2028	F2029	F2030
FFCF \$m	-\$4.2	-\$3.1	-\$1.6	\$0.1	\$1.5	\$3.2	\$4.8

As previously mentioned, **if the HCPCS code is approved in the US, it will act as a catalyst to expedite cash flow break even.**

### 8.4 Potential further upside

The company may see greater uplift from the following factors excluded from our forecasts:

1. Numerous other potential applications for NeuroStrip yet to be explored.
2. Approval of the company's HCPCS code application as previously discussed.
3. Recurring subscription revenue for data streaming via the NeuroStrip App.
4. Any future data monetisation opportunities which could be considered by the company.
5. Grants or funding.
6. Other potential jurisdictions such as Canada where patents are held.
7. Increasing our conservative assumed penetration rates.
8. Acquisitions.

Note the model removes the expected one-off ‘Impairment of Receivables for former CEO options’ as an expense moving forward.

## 9 Comparables

It's important to note that CBL has **no direct competitors on the ASX**, so we've compared it to other ASX-listed medical technology companies for relative value. These businesses vary: some have recurring revenue, some have more IP, and some lack FDA approval.

**For our comparables valuation** using LTM data, we see **CBL's valuation as \$0.21**.

As CBL and its peers are currently cash flow negative, we use 3 key metrics (EV/Sales, Price/Sales, Price/Book) which assess the relative attractiveness of these companies without skewness from negative earnings. All peers currently trade under a \$50m market capitalisation and are at a similar stage of growth and commercialisation compared to CBL.

As a cohort, there is a high degree of variability between minimum and maximum values. As a result of this, median values were considered when utilising these relative multiples.

	Mean	Median	Minimum	Maximum
EV/Revenue	65.60×	7.50×	0.18×	469.09×
Price/Sales	69.56×	8.70×	0.55×	496.11×
Price/Book	17.40×	4.44×	0.86×	73.45×

We believe these metrics fairly evaluate CBL compared to its ASX-listed peers in the medical technology sector. **We also believe CBL is likely to be undervalued.** It's also **not widely followed** by investors and CBL has a **portfolio of new growth products that are relatively unknown** in the marketplace. Additionally, the **potential of NeuroStrip remains underappreciated**, as it could be applied well beyond the core AAC market, extending into sports and clinical settings.

## 10 Share Price: CBL is deeply undervalued

With an IPO offer price of \$0.60 per share and adjusted highs of \$1.11 in December 2020, changes in sentiment have largely resulted in CBL trading at significantly lower valuations with 2022 also seeing the resignation of CEO Robert Wong due to a degenerative medical condition.

	Price	Weight
DCF	\$0.19	25%
EV/Revenue Multiple	\$0.22	25%
Price/Sales Multiple	\$0.25	25%
Price/Book Multiple	\$0.16	25%
	<b>\$0.21</b>	

Our **blended valuation model** (comprising of 3 relative valuation outcomes and 1 intrinsic valuation outcome) assumes a **share price of \$0.21** based on a weighted average price.

We believe **CBL has made significant progress on their growth strategy and firmly believe our valuations reflect the potential of the company to do well in the long-term.**

## 11 Management

### Mr. Jeremy Steele

On the 19<sup>th</sup> of January 2023, CBL announced the appointment of Jeremy Steele as Chief Executive Officer and a board member. Jeremy brings a range of experience and was formerly the Head of Private Equity at ANZ, Chairman of FastTrack, and Non-Executive Director of Aesop. Most recently, Jeremy was the Chief Executive Officer of CardioScan, a global provider of cardiac reporting with over 750k+ tests analysed per year.

### Dr. Robert Heard

2023 saw the arrival of Dr. Robert Heard as Non-Executive Director of Control Bionics. Dr. Heard has been a neurologist for more than 30 years with an extensive network across the NSW Health District. Robert was the Director of Neuropsychology at the Royal Prince Alfred Hospital, as well as Director of Neuroimmunology and Multiple Sclerosis Services at Westmead Hospital. He was also Clinical Associate Professor for the Medical Faculty at the University of Sydney (ranked 26<sup>th</sup> in the world for Medicine – QS Rankings 2024). Based on the Central Coast, Dr. Heard is currently Conjoint Professor at the University of Newcastle whilst he assists CBL.

## 12 Catalysts

- Increase of sales for NeuroNode product suite across existing (Australia, USA) and new jurisdictions (Japan, UK and select European countries).
- DROVE Australian TGA approval and clinical trials to commence in the US.
- Launch of NeuroStrip at AI for Good Conference and start of customer trials.
- First commercial sales of NeuroStrip in sports and rehab segments.
- New partnerships for standalone NeuroNode strategy in Japan and Europe.
- US and Japan breakeven expected.
- First EU sales for NeuroNode expected.
- First NeuroNode research partnerships.

## 13 Key risks

### **Regulatory Risk**

Expanding into new markets or jurisdictions may pose challenges for CBL, potentially impeding its entry into these areas and affecting both current and future revenues. The company faces regulation from various bodies, including the FDA, TGA, CE MARK, MHRA, and PMDA. Consequently, alterations in laws or regulatory requirements could directly impact product development, operations, pricing, insurance, and the competitive landscape across its range of offerings.

### **Rebate Risk**

Any unexpected changes at a federal level to NDIS in Australia and/or other jurisdictional rebate schemes could impact revenues as customers may not consider the products for purchase. This extends to America and Medicare, Medicaid, Veterans Association where a large proportion of revenues are derived from. This could also influence public perceptions of the products and newer sales, subsequently impacting prospects for revenue growth. Changes to these healthcare schemes could influence key demographics to assess alternative products, subsequently influencing sales of any CBL products.

### **Supply Chain, Manufacturing and Distribution Capability Risk**

Hardware components and manufacturing may be impacted due to unforeseen supply chain issues, increasing backlog which may delay existing orders and negatively impact consumer experience. Manufacture and sale of the core product offering is contingent on a continuity of steady supply. Any delays in manufacturing and/or manufacturing practices could have negative implications on the company. As CBL products are manufactured, quality tested in Australia there is a lower risk compared to products manufactured in cheaper jurisdictions. However, any unforeseen changes to existing and future partnerships may influence distribution networks and the ability to reach SLP's. Changes to licensing agreements with the NeuroNode and NeuroStrip products may occur in the future, which will have an adverse impact on the ability to efficiently distribute these products. This risk will extend to NeuroStrip and DROVE as further commercialisation unfolds.

### **Intellectual Property Risk**

Significant costs may be incurred from infringements or challenges by a third-party to the company's existing intellectual property. This could be encountered across CBL's entire portfolio of IP for NeuroNode. Note that CBL is well protected with multiple patents ranging from text/stylisation, use of logos, user-interfaces, EMG technology and intended audience (interactive communication and analysis). These range in a variety of jurisdictions including Australia, Japan, USA, Canada, and China whereby competitors could infringe on CBL.

### **Market Risk**

Entry into new markets will produce additional regulatory and operating risks. Competitors with better resources or stronger products may influence the company's competitive position. CBL may encounter this upon global release and commercialisation of the NeuroNode and/or DROVE products. Competition



in markets may not lead to increases in revenue upon entry, leading to decreases in working capital or changes in product/operations.

This report was written by Aditya Deshpande and edited by Joe Durak and Elvira Badke.

## **Contact Details**

Joe Durak  
Executive Director & Founder  
Lynx Advisors

+61 414 465 582

[joe@lynxadvisors.com.au](mailto:joe@lynxadvisors.com.au)

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