



Biotech Daily

Friday May 7, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.27 percent on Friday May 7, 2021, with the ASX200 up 19.1 points to 7,080.8 points.

Twelve of the Biotech Daily Top 40 stocks were up, 22 fell and six traded unchanged. All three Big Caps were down.

Nova Eye was the best, up 1.5 cents or 4.6 percent to 34 cents, with 64,346 shares traded.

LBT and Paradigm climbed four percent or more; Actinogen, Alterity and Prescient were up more than three percent; Compumedics rose 2.4 percent; Neuren, Pharmaxis and Proteomics were up more than one percent; with Genetic Signatures and Telix up by less than one percent.

Patrys led the falls, down 0.3 cents or 11.5 percent to 2.3 cents, with 14.6 million shares traded.

Pro Medicus lost 7.8 percent; Antisense was down 5.4 percent; Impedimed and Starpharma fell four percent or more; Cyclopharm and Universal Biosensors were down more than three percent; Avita, Clinuvel, Mesoblast, Next Science, Orthocell, Polynovo and Volpara shed more than two percent; Dimerix, Immutep, Kazia, Nanosonics, Oncosil and Resmed were down one percent or more; with Cochlear, CSL, Cynata, Medical Developments and Opthea down by less than one percent.

[DR BOREHAM'S CRUCIBLE: CONTROL BIONICS](#)

By TIM BOREHAM

ASX code: CBL

Share price: 69.5 cents

Shares on issue: 83,420,640 (33,295,381 in ASX escrow)

Market cap: \$58.0 million

Chief executive officer: Rob Wong

Board: Roger Hawke (chair), Mr Wong, Peter Ford (founder and executive director), Damian Lismore, Lindsay Phillips

Financials (March quarter 2021): revenue \$773,158, cash outflows \$1.028 million, cash on hand \$13.5 million, quarters of available funding 13

Major shareholders: Peter Ford 25.5%, Nightingale Partners 10.9%, Phoenix Development Fund 9.6%, Acorn Capital 5.3%, R and R Wong Holdings (family super account) 3.05%

The notion of controlling objects or functions by 'intentional thought' has long been the realm of science fiction, or perhaps the domain of spoon-bending psychics (or charlatans, take your pick).

But as with the intrepid astronauts calling home via video on the timeless 1968 classic '2001: A Space Odyssey', fiction is closer to reality than we might think.

In the case of people with speech and movement disabilities, Control Bionics demonstrates how far thought control - or, strictly speaking, control by thought - has come.

Control Bionics is a world leader in electromyography (EMG): capturing and processing the body's electric signals to fulfill a communication (or other) function.

The recently listed entity has developed - and is selling - variant devices, called Neuronode and Trilogy. These units allow users to communicate more effectively by tapping the neural (or visual) signals sent from the brain to the muscles.

The muscles don't have to be functioning; as long as the electrical signals are extant.

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

"Control Bionics is passionate about helping clients find their 'voice' and regain control of their lives," says chief executive Rob Wong.

Background

Control Bionics was founded in 2005 by Peter Ford, with the help of a \$1 million 'angel' investment from the Phoenix Development Fund. Both parties remain key shareholders.

Now in his seventies, Mr Ford was a Queensland University computer science whiz and then anchored a tech show on the US network CNN. In his downtime he worked with a US think tank on 'thought control'.

The first device iteration, Neuroswitch, was a heavier version of Neuronode.

Things got a wriggle along in 2014 after the company acquired Therapeutic Alliances Inc of the US (TTA), which owned key patents over electromyography monitors. TTA owner James Schorey is Control Bionomics' chief technology officer.

In 2016, the company launched Neuronode 3, a small and non-invasive device that uses the body's EMG signals to control a mobile phone, tablet or computer.

Mr Wong joined in January 2017 with a commercialization agenda. From a marketing background, Mr Wong had built a digital advertising catalogue business called CC Media, which was then acquired by APN Media.

As with Stanley Kubrick's sci-fi masterpiece, that one was well ahead of its time given Coles only recently ditched print 'junk mail' catalogues.

Mr Wong became involved in Control Bionics at the behest of Phoenix Development Fund, which had invested in CC Media.

Control Bionics listed on the ASX on December 7 last year, after raising \$15 million, with the 60 cents offer price being more than doubled during the day.

Building a better mouse trap

The company's flagship product is the aforementioned Neuronode 3, a watch-sized wireless neuroelectric sensor. Neuronode uses smart algorithms to convert the neuroelectric signals into code, which controls the devices.

Because the software uses signals inside a muscle, it works with no noticeable movement of the muscle. Other rival assistive technology devices require a keyboard, mouse, joystick, touch screen or eye-tracking to function.

In 2018, Control Bionics combined Neuronode with speech generating software to create Neuronode 3 and in 2019, the company launched Neuronode Trilogy, which combines eye-tracking technology with the patented Neuronode stuff.

While Control Bionics 'smarts' revolve around the electromyography (EMG) hardware and programs, it should be stressed that technology such as 'eye gaze' already exists.

With eye tracking, the peepers act as a de-facto mouse to find a cursor on the screen. But the eyes are fatigued after 15 minutes and users are confined to simple statements.

Control Bionics' key selling point is that the users can engage in more meaningful conversation because the process is so much quicker. The advantages are reinforced at a time when so many people - especially the young 'uns - communicate exclusively by non-face-to-face and non-voice means.

Thus, a disabled person can feel more included because they have the ability to fire back a reply to a text/Instagram/Facebook/Snapchat message just as quickly as an able-bodied soul.

Forging a path to market

The devices have won approval from the US, European, Canadian and Australian regulators as a medical device.

In Japan, where the products don't need to be registered as a medical device, the company is working with Jetro (Japan External Trade Organisation) on how to penetrate that market.

So far, the company has sold more than 300 units, mainly in the US and Australia.

In April, the company entered a non-exclusive US reseller deal with Numotion, which sells complex rehabilitation technology. The tie-up provides access to 150 sites across New Hampshire, Vermont and New York.

Mr Wong says Europe would have been an obvious market, "but Brexit made it all a bit messy". The products are also accredited under the Ontario Ministry of Health's assistive devices program.

Addressable market

The reality is that in this market most users don't have money to spend, so public and private reimbursement is crucial. To date, just under 80 percent of sales have been funded in this manner. Fortunately, the products are of huge interest to private and public funders including the local National Disability Insurance Scheme (NDIS).

In the US, the company devoted many management hours to getting on top of the intricacies of Medicare/Medicaid funding, as well as forming relationships with US veteran support bodies (the next biggest US health funder).

The circa \$20,000 cost of the units is in line with that of current eye gaze units of between \$15,000 and \$27,000. Currently, 20 percent of sales are for Neuronode only, which can be used for traumatic brain injury victims unable to use an eye-gazing function.

“We have tried to make it enormously flexible for a variety of people,” Mr Wong says.

The company cites an addressable market of 2.04 million users in the US, 385,000 in Japan and 82,000 in Australia.

Finances and performance

The company chalked up a creditable \$2 million of sales in the first (December) half of the 2020-'21 year.

The March 2021 quarter - the first full one as a listed entity - was off the pace, with sales of \$700,000.

Mr Wong attributes this to Covid-related sales conversion delays, changes in the NDIS approval process and “seasonality influences on insurance applications in the US”.

As a further comparison, in the 2019-'20 year the company racked up \$3.1 million of product revenue, 300 percent higher. Currently the US accounts for 65 percent of revenue; Australia the remainder.

Travel restrictions meant that operating expenses were subdued, but management cautions that costs will increase as the company builds resources in-line with the prospectus guidance.

Mr Wong estimates the company has spent \$10 million on research and development thus far. Barring an acquisition or two, the current cash of around \$13 million is likely to be enough to fund the company's immediate growth agenda.

Bionics shares roared to a close of \$1.18 on listing day, but slunk back to their 60c listing price on April 6. The stock now trades modestly above the listing price.

What's next?

Speaking of growth plans, the company is turning to miniaturizing the Neuronode tech to extend to functions such as wheelchair controls. The idea is that, rather like a reversing camera, sensors will alert wheelchair users to hazards that they might not be able to see.

For example, an object might be blocking one of their wheels, but they can't crane their neck far enough to see the obstruction and manoeuvre accordingly.

The company is also mulling electro-oculography, which detects minute eye movements to control switches even when the peepers are closed.

Other areas of interest - to varying degrees -are gaming applications (as in video games, not betting), muscle retraining rehabilitation products and epilepsy and stroke monitoring.

Dr Boreham's diagnosis:

Mr Wong says it's an interesting experience to head a small company that's gearing up for growth.

A key to success is enhancing resources in line with revenue growth. For instance, the company has appointed a chief financial officer and is moving from its modest premises in Melbourne's leafy Surrey Hills to bigger digs in nearby Hawthorn.

But it's just as crucial not to overspend on fripperies, with many minnow enterprises discovering just how non-essential much of their travel budget is.

"I have run businesses on the smell of an oily rag before," Mr Wong says, adding that as the company builds to global scale, it will also look to plumping up its five-person board.

With 56,000 people (sadly) joining the company's target market annually, opportunities abound. Given the aforementioned revenue per unit of \$22,000, it doesn't take A Beautiful Mind to calculate a \$1.2 billion opportunity.

"We are at very early stages of revenue but we want to build a global company," Mr Wong says.

And the risks? Glad you asked

As brokers Morgans notes, Control Bionics operates in a "competing and rapidly evolving" market. Competitors include Tobii Dynavox, which stemmed from the merger of Sweden's Tobii with Dynavox of the US.

"[The company] may face competitors that are far better resourced, capable of developing superior products and faster to adopt new technologies," the firm says.

Morgans expects sales to ramp up steadily to \$8.4 million in the 2022-'23 year, but with losses persisting (\$4 million on an underlying basis).

In the longer term, Mr Wong predicts the keyboard and mouse will become redundant as neuro-electric technology replaces everyday functions across the board.

Your columnist's random thoughts could jump straight from brain to screen which - come to think of it - is as scary as computers that refuse to open the pod bay door.

Disclosure (a): Dr Boreham is not a qualified medical practitioner. He does not possess a doctorate of any sort. He still can't decipher the ending of 2001 A Space Odyssey after multiple viewings, but this technophobe reckons it was one HAL of a film.

Disclosure (b): both the author and Biotech Daily editor David Langsam own Control Bionics shares.

REGENEUS

Regeneus says it hopes to raise up-to \$4.5 million, potentially starting at 20 cents a share in the next 12 months in a private placement to New Life Sciences Capital LLC.

Regeneus said it would raise funds in three stages, each planned to raise \$1,500,000 with the first “in the next week” the second within the next six months and the final placement in the next 12 months.

Under a sub-heading of ‘Further details on the placement’ the company said it would “issue placement shares in relation to all or part of each of the placements at the investor’s request, within 24 months of the date of the corresponding prepayment”.

Regeneus said the number of shares issued would be determined by applying the purchase price to the subscription amount, subject to a floor price of five cents a share.

The company said that for the first two tranches it would issue \$1,590,000 to raise \$1,500,000.

Regeneus chief executive officer Karolis Rosickas told Biotech Daily that the difference was “an implied placement fee” and the facility was “a structured equity instrument [with] a pre-payment for shares coming in three tranches, not a draw-down facility”.

Regeneus said the third placement of \$1,500,000 in shares would be for \$1,500,000.

The company said the initial share price of 20 cents a share was a 74 percent premium to the last closing price on May 6, 2021, conditional on shares being issued by July 6, 2021.

Regeneus said that shares issued after July 6, 2021 would have the share price reset to a five percent discount to the five-day volume-weighted average price selected by New Life Sciences in the 20 consecutive trading days prior to the notice to issue shares, or an eight percent discount if the shares were issued after February 1, 2022.

The company said that either party could refuse or reduce the placement if the price was unsatisfactory.

Regeneus said it would pay an initial fee of 1,352,982 Regeneus shares and 3.8 million options exercisable at 16.51 cents to New Life Sciences, as well as \$27,000 worth of shares at the time of the third placement.

Regeneus said it would use the funds for phase II US trials of its Progenza for osteoarthritis, planned to begin by July 2022, and for general working capital.

Regeneus fell 1.5 cents or 13.0 percent to 10 cents with 3.4 million shares traded.

NOXOPHARM

Noxopharm says it will enroll 40 patients in its planned phase Ib trial of Veyonda combined with doxorubicin for soft tissue sarcomas, but has not specified starting date.

Last year, Noxopharm said the US Food and Drug Administration had approved its investigational new drug application (IND) application for the phase Ib trial of Veyonda, or NOX66, and it would “explore available non-dilutive funding opportunities to enable the study to proceed” (BD: Feb 21, 2020).

Today, the company said that its \$23 million capital raise in December 2020 meant it could proceed with the study, but it would continue to seek non-dilutive funding.

Noxopharm was up nine cents or 18.6 percent to 57.5 cents with 2.7 million shares traded.

OVENTUS MEDICAL

Oventus has requested a voluntary suspension following a trading halt requested on May 5, 2021 “in relation to a capital raising” (BD: May 5, 2021).

Trading will resume on May 10, 2021 or on an earlier announcement.

Oventus last traded at 16.5 cents.

POLYNOVO

Polynovo says it has appointed Dr Joshua Cheetham as head of research and development.

Polynovo said Dr Cheetham had more than 25 years' experience in research and development, regulatory, commercialization of medical products and manufacturing operations and was previously the chief executive officer of SDI, formerly Southern Dental Industries.

The company said Dr Cheetham held a Bachelor of Engineering from the Royal Melbourne Institute of Technology as well as a Master of Business Administration AND a Doctor of Philosophy from the University of Melbourne.

Polynovo fell seven cents or 2.5 percent to \$2.78 with 1.4 million shares traded.