



# Biotech Daily

Friday July 5, 2019

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.5 percent on Wednesday July 3, 2019, with the ASX200 up 33.3 points to 6,751.3 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, five traded unchanged and four were untraded. All three Big Caps rose.

Benitec was the best, up 0.4 cents or 7.3 percent to 5.9 cents, with 1.2 million shares traded. Paradigm climbed 6.7 percent; both Dimerix and Opthea improved five percent; Actinogen, Orthocell, Patrys and Universal Biosensors were up more than four percent; LBT and Neuren were up more than three percent; Antisense, Compumedics, Pro Medicus and Telix rose more than two percent; Avita, Cochlear, CSL, Oncosil and Starpharma were up more than one percent; with Clinuvel, Cynata, Mesoblast, Polynovo and Resmed up by less the one percent.

Uscom led the falls, down one cent or 7.1 percent to 13 cents, with 100,000 shares traded. Kazia lost five percent; Resonance retreated 4.55 percent; Alterity (Prana) and Impedimed fell more than three percent; Medical Developments shed 2.8 percent; Ellex, Osprey and Volpara were down more than one percent; with Nanosonics down 0.4 percent.

## [DR BOREHAM'S CRUCIBLE: ORTHOCELL](#)

**By TIM BOREHAM**

**ASX Code:** OCC

**Share price:** 48.5 cents; **Market cap:** \$74.4 million; **Shares on issue:** 153,366,810

**Managing-director:** Paul Anderson

**Board:** Dr Stewart Washer (executive chair), Paul Anderson (M-D), Matt Callahan, Prof Lars Lidgren, Qi Xiao Zhou

**Financials (March quarter 2019):** receipts of \$303,000, cash burn \$1.26 million, cash of \$3.24 million\*, estimated June quarter outflows \$1.63 million

\* The company raised a further \$10.6 million in a placement in June 2019.

**Identifiable shareholders:** Paul Anderson and Nicole Telford 4.6%, Stone Ridge Ventures Custodians (Australian Super) 5.49%, Ming Hao Zheng and Ying Fan 5.06%, Matt Callahan 5.63%, Qi Xiao Zhou 5.44%, Jia Xun Xu 4.69%.

Here's one that investors can really get their teeth into: Orthocell's regenerative therapy Celgro quickens and improves dental implant procedures and repairs jangled nerves in more ways than one.

To the joy of Collingwood supporters\*, the Perth-based regenerative medicine outfit last month announced that 10 patients in a marketing study were able to enjoy a normal diet after suffering damaged missing or diseased teeth.

While Celgro's dental applications are certainly something to chew on, investors reserved their zeal for the interim, four-patient results of an open label study for peripheral nerve repair, announced in early May, which showed nerve regeneration.

Orthocell chief Paul Anderson says the ensuing 450 percent share price romp reflects investor recognition of both the nerve results and Celgro's potential as a platform technology.

"The market was excited by the nerve piece but they are looking further and saying this is a company that should be valued higher," he says. "All the results are more significantly advanced than anything in the market."

Orthocell's mission is to develop and commercialize cell therapies and related technology to treat soft tissue injuries and musculoskeletal disorders.

Orthocell was founded in 2006 by Mr Anderson and chief scientific officer Prof Ming Hao Zheng, former CEO of cell therapist Verigen. Having obtained earlier seed funding, Orthocell listed in August 2014 after raising \$8 million at 40 cents apiece.

## **About Celgro**

Celgro is a naturally-derived collagen, originally from pigs, that forms a lattice to promote tissue growth and nerve regeneration. It has applications in tendons, peripheral nerve, bone and joint cartilage repair, as well as broader general surgical and soft tissue reconstructive uses. Celgro has also undergone pre-clinical evaluation as a collagen 'rope' for anterior cruciate ligament reconstructions.

"We took a risk to develop Celgro as a platform, it means we have taken slightly longer to get traction," Mr Anderson says. "But we see incredible value in the platform as a whole, whether in bone, ligament or nerve repair."

Europe's medical gatekeepers approved Celgro for dental bone and soft tissue (facial) applications in early 2018.

## **Nerve-tingling moment**

Orthocell touched the desired nerve with investors when it revealed that the first four patients of the 20-strong trial regained muscle function and/or sensation of the affected limbs after 24 months' treatment. They also experienced an average 83 percent improvement in muscle power.

The subjects had severed peripheral nerves in the hands and upper limbs, the result of traffic, work or sporting mishaps. The patients had suffered traumatic pain and had been unable to perform activities such as eating, bathing and toileting.

Celgro is secured around nerve ends, forming a sealed conduit to allow new fibres to reconnect. A key feature is that it is 'tensionless', which means there's no use of sutures (stitches) that can further damage soft tissue.

"The nerve injuries suffered by the patients in this trial were so severe that they would not have been able to regain normal use of their injured arm and hand without microsurgery," says orthopaedic nerve specialist Dr Alex O'Beirne of Perth's St John of God Subiaco Hospital.

In early 2018, a 72-patient study of patients with dodgy anterior cruciate ligaments showed "superior biomechanical properties". Carried out with the University of Western Australia, the study showed the Celgro rope was equal to, or better than, the use of tissue typically harvested from hamstrings.

The company is now preparing Australian and US regulatory submissions.

## **Chewing over the dental potential**

The Celgro dental trial showed the 10 patients - not all of whom were Collingwood supporters - generated enough new bone to stabilize their implants and complete treatment in just over four months after the single-stage treatment.

In comparison, traditional guided bone regeneration treatment involves two procedures over eight months: the first to install the implant into the jaw and the second to place the implant abutment to the prosthetic tooth.

With Celgro the implant and abutment can be placed at the same time.

The marketing study was carried out in partnership with Perth maxilla-facial surgeon Prof Dr Brent Allan and the University of Western Australia's and Orthocell's Prof Zheng.

### **Orthocell's other products**

Orthocell's older products are Ortho-ATI and Ortho-ACI, which use the patients' own tissue to stimulate the growth of collagen and connective tissues. Both are approved for use in Australia, New Zealand, Singapore and Hong Kong under good manufacturing practice protocols.

Ortho-ATI (as in autologous tenocyte implantation) is for chronic tendon degeneration resistant to other therapies, as evidence in gluteal tendinopathy (a common form of hip pain) and tennis elbow.

The company recently met with the US Food and Drug Administration with a view to lodging an investigational new drug application and Mr Anderson is heartened by the FDA's revised stance on approving cell therapies, which requires safety and good manufacturing practice, while letting the market decide what therapy works and what doesn't.

"The FDA realizes that applying phase I to III clinical trial requirements for cellular therapies means that you are never going to get anything to market," he says.

In the meantime, Orthocell is undertaking a 30-patient randomized trial with DePuy Synthes Products (Johnson & Johnson's orthopaedics arm) to treat rotor cuff tendinopathy with Ortho-ATI rather than with corticosteroid injections, and begun its own 50-patient trial comparing Ortho-ATI with traditional surgery.

### **Hush-hush on Ortho-ACI**

Orthocell doesn't mention Ortho-ACI these days - not because the treatment has been unsuccessful but because it's a case of one product too many for investors to comprehend.

Orthocell-ACI (as in autologous chondrocyte implantation) repairs articulating joint cartilages, mainly in the knee and ankle and replaces painful tendon grafts. The treatment has been used on more than 700 patients locally and in Singapore and Hong Kong.

"It's a fantastic product but when you want to articulate a story to the market it's incredibly hard for people to get their head around so many products," Mr Anderson says. "We have made a strategic decision not to talk about Ortho-ACI, but let it bubble on below the surface."

## Finances and performance

Orthocell's revenue has been modest to date - just over \$300,000 in the March quarter - but sales have been more about validating the company's technology and manufacturing processes. Having raised \$3 million in a placement and share purchase plan in early 2018, Orthocell has gone to the well again by raising \$10.6 million in a placement, at four cents apiece.

"The raising gives us a pathway for the next 24 months to enable us to achieve the goals we have set out," Mr Anderson says.

If Orthocell is not acquired, the company expects to sell its products via distributorships, licencing or other arrangements.

"It's just not viable for a company of our size to do it on our own," Mr Anderson says.

Orthocell shares legged it up to 92 cents in mid-2015 and flopped to a low of 11.5 cents on May 7. The stock then jumped to 64 cents after the May 8 nerve trial results.

### Dr Boreham's diagnosis:

Orthocell likens its potential to that of the home-grown, ASX-listed Polynovo, which is now valued at around \$1 billion.

Polynovo's approved wound-repair scaffold product Novosorb is also relevant for other procedures including hernias and breast augmentations.

"They are a great company - but they only have the one product," Mr Anderson says.

Orthocell has made great strides in devising more effective treatments for the defective cartilage and tissues that Our Maker bestowed us. The knee, in particular is a tenuous strip of tissue (the anterior cruciate ligament) that connects the thigh bone (femur) to the shin bone (tibia). If it were a product, the consumer watchdog would recall it.

Orthocell estimates a \$US600 million (\$A870 million) global market for nerve regeneration, \$US900 million for tendons and soft tissues and more than \$US1.1 billion for peripheral nerve repair, with 700,000 annual procedures likely to benefit from Celgro.

Despite Orthocell's dramatic share price increment, its circa \$80 million market cap suggests there's plenty left on the table for newcomers to the stock. Nerve repair adds that extra zing that could take the company to the next level.

\* For overseas readers, Collingwood is a working-class Australian Rules football club synonymous with supporters lacking the requisite number of incisors and with poor dental hygiene.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Happily, he still has a full set of teeth, which explains why he doesn't barrack for Collingwood.***

## [NUHEARA](#)

Nuheara has told the ASX that Samsung's wholly-owned subsidiary Harman International Industries made the withdrawn \$82.5 million acquisition bid.

On Wednesday, Nuheara said an unnamed consumer electronics company offered it \$82,505,665 or 8.4 cents a share to acquire it in April (BD: Jul 3, 2019).

The company said at that time that the electronics company withdrew the bid after being told its name and letter of intent would be provided in a capital raising cleansing notice.

Today, the ASX said an article entitled 'Samsung pulls bid for Perth start-up' was published in the Australian Financial Review on July 4, 2019 and asked the company if the information was accurate, "in particular the identity of the counterparty to the offer".

Nuheara said the information was not accurate and that Samsung subsidiary Harman was the counterparty, which "operates separately from Samsung and conducts its own business".

The ASX said an announcement titled 'Nuheara update to market' was released on its announcement platform on June 25, with a further capital raising trading halt announcement released on July 3, 2019 and asked the company why it did not disclose details of the offer on June 25.

The company said it did not disclose details because it "needed to conduct limited confidential soundings with potential investors".

Nuheara said it was not aware of how the Financial Review formed a view of the identity of Samsung in the offer and claimed it did not disclose Harman or Samsung's identity to any party participating in the capital raising.

Nuheara was up half a cent or 9.1 percent to six cents with 11.7 million shares traded.

## [NUHEARA](#)

Nuheara says it has raised \$4 million at five cents a share, a 9.1 percent discount to the closing price on July 2, 2019.

Nuheara said the placement was institutional and sophisticated investors included major shareholder, the Sydney based Farjoy Pty Ltd, with 80 percent raised from existing shareholders.

The company said the funds would be used to increase sales and marketing to support its products and accessories.

Nuheara said Rawson Lewis was the lead manager to the placement.

## [SHAREROOT](#)

Shareroot says it will divest its Ludomade games and promotional applications for entertainment and consumer goods business to focus on digital health.

Shareroot said it acquired Ludomade in November 2018 but a review of operations found that it was "non-core to Shareroot's future strategic direction and should therefore be divested to eliminate distraction and consumption of resources".

Shareroot was unchanged at 0.1 cents with 2.6 million shares traded.

## [COGSTATE](#)

Cogstate has requested a trading halt "pending an announcement by the company to the market in relation to a proposed placement".

Trading will resume on July 9, 2019 or on an earlier announcement.

Cogstate last traded at 15.5 cents.

### IMMUTEP

Immutep has requested a trading halt “pending an announcement in relation to a potential capital raising”.

Trading will resume on July 9, 2019 or on an earlier announcement.

Immutep last traded at 2.5 cents.

### MEMPHASYS

Memphasys has requested a trading halt pending an announcement regarding a proposed “equity capital raising”.

Trading will resume on July 9, 2019 or on an earlier announcement.

Memphasys last traded at 3.1 cents.

### IMPEDIMED

Macquarie Group and related parties say they have ceased their substantial shareholding in Impedimed.

Last month, the Sydney-based Macquarie Group said it became substantial with 18,993,265 shares or 5.00 percent of Impedimed (BD: Jun 26, 2019).

Today, Macquarie Group said that between June 24 and July 2, 2019 it bought and sold shares at prices ranging from 11 to 13 cents a share and transferred out and in 12,504 shares at no cost on June 27, 2019.

Impedimed fell half a cent or 3.6 percent to 13.5 cents with 1.1 million shares traded,

### ADALTA

Yuuwa Capital says it has been diluted in Adalta with 54,059,848 shares from 39.4 percent to 32.9 percent.

The Nedlands, Western Australia-based Yuuwa said it was diluted in the \$5 million placement and \$2 million rights issue at 15 cents a share (BD: May 23, June 14, 2019).

The substantial shareholder notice was signed by Yuuwa general partner and Adalta director Elizabeth McCall.

Adalta was up one cent or 6.9 percent to 15.5 cents.