



Biotech Daily

Friday March 16, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMPEDIMED UP 6%; OPTISCAN DOWN 8%**
- * **DR BOREHAM'S CRUCIBLE: ORTHOCELL**
- * **OPTISCAN BOARD SPILL REQUEST**
- * **GENETIC TECHNOLOGIES, MELBOURNE UNI WORK ON BREVAGENPLUS**
- * **RACE RAISES FURTHER \$480k, TOTAL \$3.6m**
- * **NUHEARA APPROVED FOR GOVERNMENT HEARING PROGRAM**
- * **MAYNE LAUNCHES DOXYCYCLINE FOR ACNE CAPSULES IN THE US**
- * **MICRO-X REQUESTS 'CAPITAL RAISING' HALT**
- * **DIRECTOR ANDREW KROGER TAKES 35.5% OF CRYOSITE**
- * **CRYSTAL AMBER TAKES 47.5% OF GI DYNAMICS**
- * **DOUG HALLEY REPLACES MMJ DIRECTOR JASON BEDNAR**

MARKET REPORT

The Australian stock market was up 0.48 percent on Friday March 16, 2018, with the ASX200 up 28.5 points to 5,949.4 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Impedimed was the best, up four cents or 5.6 percent to 75 cents with 225,638 shares traded. Clinuvel, Opthea and Reva climbed more than five percent; Psivida and Universal Biosensors improved more than four percent; Compumedics and Cyclopharm were up more than three percent; Actinogen, Airxpanders, Benitec and Pharmaxis rose two percent or more; Avita, Bionomics, Cochlear, Ellex, ITL and Mesoblast were up more than one percent; with CSL, Resmed, Starpharma and Volpara up by less than one percent.

Optiscan led the falls on a board spill call (see below), down 0.6 cents or 7.7 percent to 7.2 cents with 486,000 shares traded. Dimerix lost 7.1 percent; Factor fell 4.65 percent; Acrux, Genetic Signatures, Immutep and Orthocell were down more than three percent; Medical Developments, Osprey and Pro Medicus shed more than two percent; Polynovo and Uscom lost one percent or more; with Neuren and Sirtex down by less than one percent.

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

By TIM BOREHAM

ASX Code: OCC

Share price: 29 cents

Market cap: \$31.9 million

Shares on issue: 109,964,253

Chief executive officer: Paul Anderson

Board: Dr Stewart Washer (chair), Paul Anderson (CEO), Matt Callahan, Prof Lars Lidgren, Qi Xiao Zhou

Financials (December half): revenue \$377,620 (down 6.0%), loss \$943,274 (down 67%), cash \$4.9 million (down 19%)*

* Before \$3 million placement and share purchase plan

Identifiable shareholders: Ming Hao Zheng/Ying Fan 6.72%, Paul Anderson 6.35%, Matt Callahan 9.29%, Qi Xiao Zhou 5.45%.

While the Greater Powers** did a pretty decent job with our main organs and brains and all that, they made shoddier work of the cartilage and tissues that hold us together.

The knee, in particular, must have come off Our Creator's production line at 4.45pm on a Friday arvo.

Even the worst Kingswoods in the 1970s were better constructed than the anterior cruciate ligament (ACL), the tenuous strip of tissue that connects the thigh bone (femur) to the shin bone (tibia).

ACLs are the bane of sportspeople globally, with 100,000 to 200,000 ACL ruptures annually in the US alone.

You can also add 250,000 rotator cuff (shoulder) and 200,000 Achilles tendons to that market annually.

Perth-based regenerative medicine house Orthocell is striving to rectify Our Creator's shoddy work, as it develops and commercializes cell therapies and related technology to treat soft tissue injuries and musculoskeletal disorders.

Orthocell was founded in 2006 by current chief executive officer Paul Anderson and chief scientific officer Prof Ming Hao Zheng, former chief executive officer of cell therapist Verigen (which the US-based Genzyme acquired in 2005).

Having obtained earlier seed funding, Orthocell listed in August 2014 after raising \$8 million at 40 cents a share.

“We are a mature company with lots of boxes ticked in lots of areas,” Mr Anderson says.

Orthocell’s products

Orthocell’s current products - autologous tendon implants (Ortho-ATI) and autologous chondrocyte implants (Ortho-ACI) - involve novel uses of the patient’s own, that is autologous, tissue, namely tendon progenitor cells, to stimulate the growth of collagen and connective tissues.

Both products are approved for use in Australia, New Zealand, Singapore and Hong Kong under good manufacturing practice protocols. Ortho-ATI is approved in the US, Europe, China and Japan and was said to be the first autologous cell therapy for tendon and ligament repair approved for sale in a major market.

The company’s product in development, Celgro, is a naturally-derived collagen for soft tissue repair. It is expected to have applications in tendons, peripheral nerve, bone and articular (joint) cartilage repair.

Celgro, has undergone pre-clinical evaluation as a collagen ‘rope’ for ACL reconstructions.

The idea is that stem cells from the remains of the ACL grow into the rope and eventually integrate with the bone, creating a tensile strength similar to the natural ligament.

Ortho-ATI is for chronic tendon degeneration resistant to other therapies.

Clinical trials and case studies to date suggest the therapy hastens tendon healing and reduces pain and stiffness. So far Ortho-ATI has been effective against gluteal tendinopathy (a common form of hip pain) and “extensor carpi radialis brevis”.

That’s tennis elbow to you and me.

Orthocell-ACI is for repair of articulating joint cartilages, mainly in the knee and ankle. It is hoped the procedure will be globally accepted as more effective and less painful than the traditional alternative of an autologous tendon graft.

So far, about 1,000 patients have been treated with Ortho-ATI or Ortho-ACI - roughly evenly split between the therapies - in Australia, New Zealand, Singapore and Hong Kong.

In a key milestone, last November, Orthocell obtained Conformité Européenne (CE) mark approval for use of Celgro for dental (bone) and facial (soft tissue) applications.

The company estimates the global dental market alone at \$US600 million with 1.5 million procedures a year.

Unlike Orthocell’s other products, Celgro is regarded as a class-three-device rather than a cell therapy, because Celgro takes an animal raw material and processes it into various therapeutic tools. This means a “simple and more linear” path to market.

“Celgro is a platform technology with multiple applications in multiple tissue types,” Mr Anderson says. “It is a big market with easier access to market.”

In the clinic

In early February, Orthocell said the top-line results of a preclinical ACL study of Celgro indicated “superior biomechanical properties”.

The study of 72 patients - half treated with Celgro and half with traditional autografts - showed that ligament stem cells from the ACL stump were capable of growing into the Celgro rope.

The purpose of the study, in conjunction with the University of Western Australia, was to show that the Celgro rope was equal or better than the use of autologous grafts from tissue typically harvested from hamstrings (which can result in the patient enjoying restored knees but then ‘doing a hammy’).

Mr Anderson says the data also supports Celgro’s potential as an off-the-shelf treatment across multiple indications including bone, tendon and peripheral nerves.

Celgro also won a good rap from Freddie Fu from the Pittsburgh School of Medicine.

Freddie Who? The rock star of orthopaedic surgery, Prof Fu has been entrusted to treat the knees of high-profile athletes including Zlatan Ibrahimovic. It must have worked, because the Manchester United striker arrived at training the other day in a GBP210,000 Porsche.

In the case of Ortho-ATI, recruiting is underway for a 30-patient, randomized trial aiming to replace corticosteroids to treat rotor cuff tendinopathy. This program is in collaboration with DePuy Synthes Products, an arm of Johnson & Johnson.

In December, Orthocell reported a case study of swimmer Christian Sprenger treated with Ortho-ATI for shoulder tendon pain, which enabled him to return to competition.

(By the way, most sportspeople don’t want to admit to dodgy knees and shoulders, especially at contract renegotiation time).

In September, the company reported the safety and efficacy of the first three patients treated with Celgro for hip joint cartilage degeneration. This one was in league with prominent orthopaedic surgeon Dr John O’Donnell, at Melbourne’s St Vincent’s Hospital.

Now for the revenue ...

In January, Orthocell boosted its coffers with a \$3 million placement and share purchase plan. The funds will be used to further US trials, accelerate the Celgro commercialization and advance development of Ortho-ATI.

Revenue has been modest to date, derived from local Ortho-ACI and Ortho-ATI sales. Mr Anderson says the company does not have a sales force in Australia, so the product take-up to date should be seen more as validating the technology and the TGA-approved, Perth manufacturing facility.

“The fact we have treated 1,000 patients means we have been able to optimize our manufacturing process, which is incredibly important for those large international partners,” Mr Anderson says.

“Our approach is to validate locally but commercialize internationally. After all, there are more people in Texas than Australia.”

Orthocell shares legged it up to 92 cents in mid-2015, but in the last year they've traded in a range of 28 cents to 50 cents.

Dr Boreham's diagnosis:

Like Cynata (ASX: CYP) which we covered recently, Orthocell's valuation is only a fraction of that of stem-cell leader Mesoblast (ASX: MSB).

Locally, Orthocell is perhaps better compared with Admedus (ASX: AHZ), which has developed scaffold products for heart and vascular repair.

As usual there's a flattering Nasdaq comparison: Vericel, which has one ACL product and bears a \$US400 million market cap.

In October last year Smith & Nephew acquired the private medical scaffold outfit Rotation Medical for up to \$US210 million.

Orthocell is not for weak-kneed investors. Crucible would like to see more revenue through the door and, of course, more regulatory breakthroughs including US approval.

The company is due to start selling Celgro in Europe this month, but meaningful sales will take time to build.

Orthocell is discussing commercializing Celgro with a European partner and is having similar deep and meaningful with parties in the US, Japan and here.

Given the recent global takeover activity in the biotech sector, we'll class Orthocell as a possible target.

** Your columnist is ecumenical and could be talking about Mother Nature.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he does possess two knees that still perform the task His Creator intended.

OPTISCAN IMAGING

Optiscan says it has received a call from a board spill from shareholders including former chief executive officer Archie Fraser.

Mr Fraser unexpectedly resigned from Optiscan earlier this year, having been appointed in 2016 (BD: May 13, 2016; Jan 22, 2018)

In January, Optiscan said that Mr Fraser joined the company “a little less than two years ago and in that time led the company to an increase in market capitalization from \$4 million to approximately \$45 million and leaves the company in a sound position both in terms of its balance sheet and the progress of its commercialization of the Optiscan technology”.

Today the company said the board spill was called by Ibsen Pty Ltd (the Narula family), company founder and inventor Peter Maxwell Delaney, Archie Fraser Pty Ltd and IT IS Consulting Pty Ltd (Wymant family).

According to last year’s annual report the group holds 12.67 percent of the company.

Optiscan said that the board spill resolutions call for the removal of chairman Alan Hoffman and directors Peter Francis, Dr Ian Griffiths and Dr Philip Currie, to be replaced by Mr Fraser and Ron Grey.

The announcement made no mention of director Ian Mann.

Optiscan fell 0.6 cents or 7.7 percent to 7.2 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it will work with the University of Melbourne to further develop and enhance its Brevagenplus breast cancer risk assessment test.

Genetic Technologies said the research and services agreement with the University was “an important first step as the company seeks to actively expand its strategic partnerships and develop a pipeline of new genomic tests”.

The company said it would expand its tests beyond the existing breast cancer risk test and the colorectal cancer risk test under development.

Genetic Technologies said that research at the University of Melbourne would be led by the Centre for Epidemiology and Biostatistics’ Prof John Hopper and his research team.

The company said that the research was designed to broaden the applicability of the Brevagenplus breast cancer risk assessment test enabling its use by women with an extended family history of disease and would increase the range of risk factors analyzed. Genetic Technologies said that the collaboration was designed to further improve doctors’ ability to manage breast cancer by improving the accuracy of risk prediction.

The company said that breast cancer was the most common form of cancer affecting women and about one in eight women in the US and Australia would develop the disease in their lifetime.

Genetic Technologies said that targeted application of current chemoprevention, screening and lifestyle prevention measures based on the new risk assessment test “could further improve outcomes for breast cancer”.

Prof Hopper said the agreement “provides us with the basis to translate our scientific work into the clinical arena”.

“Risk stratification of patients to improve breast cancer screening and prevention has significant potential upside benefit for both women and the health system,” Prof Hopper said.

Genetic Technologies said that preliminary data from the study was expected by July 2018.

Genetic Technologies was unchanged at 1.1 cents with 14.1 million shares traded.

RACE ONCOLOGY

Race says its “heavily oversubscribe” placement has raised a further \$480,000, taking the total raised to \$3,639,060.

On Monday, said it raised \$3,159,060 through a “heavily oversubscribed” placement to professional and sophisticated investors at 32 cents a share (BD: Mar 12, 2018).

Race was up one cent or 2.9 percent to 35 cents.

NUHEARA

Nuheara says it has been registered as an approved supplier to the Australian Government’s Hearing Services Program.

Nuheara said the program was allocated \$539 million in the 2017-'18 Federal Budget and responsible for about 70 percent of the Australian hearing services market, providing eligible Australians access to free and subsidized hearing devices and related services.

The company said that more than three million Australians had some form of hearing loss and 70 percent of those were in the mild to moderate category.

Nuheara said it would place its Lq buds and Lq buds Boost on the device schedule as assisted listening devices.

Nuheara chief executive officer Justin Miller said the registration was “a significant development for the company, demonstrating its innovative hearing solutions have been recognized as a cost-effective option by the Australian Government”.

“This secures Nuheara’s mainstream position in the rapidly changing global hearing health care market,” Mr Miller said.

“We are ready to fill a massive market gap by providing [a product] that is much more affordable and one which is more visually appealing and functional, an intelligent wireless earbud that also allows you to listen to music and take phone calls,” Mr Miller said.

Nuheara was up 3.6 cents or 36.4 percent to 13.5 cents with 115.7 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has launched doxycycline monohydrate immediate release (IR) for acne in 50mg, 75mg and 100mg capsules in the US.

Mayne said that the capsules were a generic alternative to Monodox, a tetracycline-class antibacterial indicated for the treatment of a number of infections, including adjunctive therapy in severe acne.

Mayne chief executive officer Scott Richards said the launch would “further broaden Mayne Pharma’s dermatology portfolio of branded and generic products”.

The company said that US sales of doxycycline IR capsules amounted to \$US30 million for the 12 months to January 31, 2018.

Mayne fell two cents or 2.6 percent to 74.5 cents with 5.8 million shares traded.

MICRO-X

Micro-X has requested a trading halt “pending the release of an announcement to the market in relation to a capital raising”.

Trading will resume on March 20, 2018 or on an earlier announcement.

Micro-X last traded at 40 cents.

CRYOSITE

Cryosite director Andrew Kroger says he has increased his substantial shareholding from 16,016,906 shares (34.18%) to 16,642,791 shares (35.52%).

Mr Kroger said the shares were bought on-market on March 14, 2018 and 10 cents and 11 cents a share.

Mr Kroger said that the shares were held directly and through Austen Bay Pty Ltd acting for the Andrew Kroger superannuation fund, SHR Pty Ltd and Process Wastewater Technologies Pty Ltd.

Cryosite was untraded at 11 cents.

GI DYNAMICS

The Crystal Amber Fund says it has increased its holding in GI Dynamics from 262,245,605 shares (44.73%) to 292,756,452 shares (47.47%).

The London and Guernsey Island-based Crystal Amber Fund said that between February 8 and March 15, 2018 it bought 30,510,847 shares for \$1,063,180 or an average of 3.48 cents a share.

GI Dynamics was untraded at 3.2 cents.

MMJ PHYTOTECH

MMJ says it has appointed Doug Halley as a director, effective immediately, replacing Jason Bednar.

MMJ said that Mr Halley was an experienced company director and most recently was the Duet Group chairman.

The company said that Mr Bednar had retired from the MMJ board and would remain an independent non-executive director of Canadian investee company Harvest One Cannabis.

MMJ was up half a cent or 1.2 percent to 41 cents.