



Biotech Daily

Thursday June 12, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: COMPUMEDICS UP 15%, OPTISCAN DOWN 14%**
- * **ORTHOCELL ORTHO-ATI TENDON PAIN PILOT TRIAL: 'SAFETY, EFFICACY'**
- * **MAISON DE BEAUTÉ TAKES LE MÉTIER PHOSPHAGENICS RANGE**
- * **COGSTATE SIGNS FIRST PRECISION RECRUITMENT CLIENT**
- * **UP TO 34% OF UNIVERSAL BIOSENSORS OPPOSE AGM VOTES**
- * **GENERA PLEADS REPORTS TO ASX 47.5% QUERY, 120% TO GO**

MARKET REPORT

The Australian stock market fell 0.46 percent on Thursday June 12, 2014 with the S&P ASX 200 down 25.2 points to 5,428.8 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and two were untraded.

Compumedics was the best, up two cents or 15.4 percent to 15 cents with 78,461 shares traded.

Atcor, Biotron, Oncosil and Psivida climbed more than four percent; Ellex was up 3.1 percent; Alchemia, Circadian and GI Dynamics rose more than two percent; Cochlear was up 1.1 percent; with Resmed and Starpharma up less than one percent.

Optiscan led the falls, down 0.5 cents or 14.3 percent to three cents with 277,882 shares traded.

Universal Biosensors lost 8.1 percent; Prana was down 6.8 percent; Analytica and Prima fell four percent or more; Acrux, Benitec, Clinuvel and Osprey shed more than two percent; Bionomics, Nanosonics, Pharmaxis, Phosphagenics and Tissue Therapies were down more than one percent; with CSL, Medical Development, Mesoblast and Sirtex down by less than one percent.

ORTHOCELL

Orthocell says a 12-patient pilot study of its Ortho-ATI tendon cell treatment for hip tendon pain has demonstrated long-term efficacy and safety.

Orthocell said that data on its Ortho-ATI or autologous tenocyte implantation for the common hip tendon injury, gluteal tendon degeneration or tendinopathy, was presented at the European Federation of National Associations of Orthopaedics and Traumatology in London, June 4 to 6, 2014.

The company said that the study was led by Perth Orthopaedic and Sports Medicine Centre orthopaedic surgeon Dr Greg Janes with visiting fellow Dr Tom Bucher and investigated the effect of Ortho-ATI in 12 patients all of whom were assessed by an independent and blinded therapist pre-operatively and at three, six, 12 and 24 months post-procedure.

Orthocell said that patients had an average symptom length of 33 months and had exhausted all available treatment options without success.

The company said that Ortho-ATI significantly improved the clinical outcome of patients with gluteal tendinopathy, showing reduced pain and increased functionality.

Orthocell said that patients completed a satisfaction questionnaire at two years post-procedure which showed 67 percent patients were satisfied or highly satisfied with the outcome of their treatment.

Dr Janes said the data "supports the potential for Ortho-ATI to provide a disease modifying intervention for gluteal tendinopathy that until now has been resistant to treatment".

Orthocell said that gluteal tendinopathy was a disabling condition that predominantly affected middle-aged and older women and previously was treated with steroid injections to alleviate pain and until recently there was no treatment directly targeting the cause of the condition.

The company said its Ortho-ATI was a tissue engineering technique using a patient's own tendon cells, or tenocytes, to assist in the repair and regeneration of damaged tendons or ligaments and had Australian Therapeutic Goods Administration approval to manufacture and sell Ortho-ATI in Australia, New Zealand and TGA-affiliated countries in Asia

Orthocell managing-director Paul Anderson said the results were encouraging for gluteal tendinopathy and a range of other hard-to-treat musculoskeletal conditions and injuries, where tendon degeneration was prevalent.

"The world population is rapidly ageing and associated musculoskeletal conditions will place an enormous financial burden on many global economies," Mr Anderson said.

"To counteract the financial impact of age-related illnesses and injuries, we need to be smarter in our approach to treating patients and create less invasive and more cost-effective procedures," Mr Anderson said.

Mr Anderson said that one of the main themes from the London meeting was the role that regenerative medicine in reducing the financial impact of age-related injuries and illnesses.

Last week, Orthocell opened its initial public offer to raise up to \$8 million at 40 cents a share, which closes on June 27, 2014 (BD: Jun 5, 2014).

Orthocell said that the funds raised would be primarily for the European and US regulatory processes for its autologous tenocyte implants (Ortho-ATI) and autologous chondrocyte implants (Ortho-ACI), as well as to develop its pig-based collagen scaffold for soft tissue reconstruction indications, including pelvic floor reconstruction, vaginal defects, ear drum repair and bladder wall defects.

PHOSPHAGENICS

Phosphagenics says Maison de Beauté LLC will distribute its cosmetics range having acquired the key skin-care assets of the bankrupt Le Métier de Beauté.

Last month, Phylogica, which also had a cosmetics deal with Le Métier De Beauté to formulate and market glycinamide into a cosmetic product for sunburn, said the New York-based parent company Le Metier Tribeca had filed for bankruptcy (BD: May 16, 2014).

In 2009, Phosphagenics signed a cosmetics distribution deal with Le Métier Tribeca which was expanded from two to 10 products in 2011 (BD: Jul 20, 2009; Jan 27, 2011).

Today, Phosphagenics said that the sale to the US based Maison de Beauté (House of Beauty) was approved in late May after Le Métier De Beauté (The Trade of Beauty) entered into "a voluntary Chapter 11 re-organization process in February 2014".

Biotech Daily has attempted to locate Maison de Beauté, finding several shops of that name in Austin Texas and New Orleans, but no website.

A Phosphagenics spokesman told Biotech Daily that Maison de Beauté was a private US company and he had no further details.

Phosphagenics said it was involved in close discussions with Le Métier De Beauté management, who had been retained under the asset sale, throughout the process.

The company said that Maison de Beauté would expand the promotion and distribution of the skincare line containing its tocopheryl phosphate mixture or TPM technology.

Phosphagenics said that Maison de Beauté had paid in full the \$US325,000 (\$A346,655) owed in unpaid royalties, to date.

Phosphagenics chief executive officer Harry Rosen said the sale "provides an excellent opportunity for Phosphagenics ... and [Le Métier De Beauté] is a significant partner in Phosphagenics' strategy to grow its revenue from the use of TPM in skincare products".

Phosphagenics fell 0.1 cents or 1.2 percent to 8.3 cents.

COGSTATE

Cogstate says it has signed a \$US1.8 million (\$A1.9 million) two-year contract for its Precision Recruitment web-based patient recruitment tool for clinical drug trials.

Last week, Cogstate unveiled Precision Recruitment "to reduce the cost and time incurred for drug companies when recruiting patients for clinical trials" (BD: June 6, 2014).

The company said that most patient pre-trial screening took place on-site and was a slow, expensive and inefficient process, but Precision Recruitment allowed patients to be tested and screened at home before being asked to join a clinical trial.

Cogstate said that potential participants were identified by the pharmaceutical company and asked to perform a series of online tests on its web portal and following the test, patients were asked to either enter the next stage of recruitment or, for those not appropriate for inclusion in the trial, be asked to join Cogstate's cognition registry, a database tracking changes in cognitive function over time.

Cogstate chief executive officer Brad O'Connor said patient recruitment delayed the average clinical trial by nearly five months with each lost day costing drug companies at least \$600,000 in forgone revenue.

"As drug companies focus their research on halting Alzheimer's disease in its earliest stages, finding and recruiting the right patients becomes vital," Mr O'Connor said.

Cogstate said that Precision Recruitment had applications for drug trials in dementia and cognitive impairment, with an increasing number of clinical trials of drugs treating psychosis, cancer, depression and stroke including cognitive impairment as an inclusion criterion.

Cogstate was up half a cent or two percent to 25.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensor's annual general meeting saw strong dissent against all resolutions with up to 33.9 percent voting against the re-election of director Denis Hanley.

All five Universal Biosensor resolutions faced strong opposition with Mr Hanley being re-elected with 60,717,849 votes (66.1%) in favor and 31,134,014 shares (33.9%) against. The re-election of director Chris Smith and chief executive officer Paul Wright, along with the senior executive remuneration and the grant of 60,000 free options with a zero exercise price and 2,040 US shares to Mr Wright were passed with more than 70.5 million votes in favor and more than 21.3 million votes against.

The company's most recent Appendix 3B new issue announcement said that Universal Biosensors had 175,353,134 Chess depositary interests on issue, meaning that the votes against Mr Hanley amounted to 17.8 percent of the company, sufficient to requisition extraordinary general meetings.

In publishing its notice of annual general meeting to the ASX on April 14, 2014, Universal Biosensors entitled it 'Definitive proxy statement', rather than as a 'Notice of meeting' as it had in previous years.

Universal Biosensors fell 1.5 cents or 8.1 percent to 17 cents with 78,250 shares traded.

GENERA BIOSYSTEMS

Genera has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price climbed from 20 cents on June 4 to 29.5 cents, a 47.5 percent increase, today June 12, 2014 and noted an increase in trading volumes.

Genera said that "a broker initiation research report was published yesterday afternoon by Lodge Partners and additionally after market close yesterday a further research note was published on the company in the Eureka Report which may explain increased interest in the company's shares".

The Lodge report, authored by biotechnology analyst Marc Sinatra, put a target price of 65 cents on Genera.

Genera closed up three cents or 13.0 percent at 26 cents with 1.4 million shares traded.