



Biotech Daily

Wednesday April 16, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ANTEO UP 12.5%, CIRCADIAN DOWN 11%**
- * **ORTHOCELL IPO FOR TENDON, CARTILAGE, SOFT TISSUE REPAIR**
- * **DRAWBRIDGE PHASE I PHAXAN ANAESTHETIC SAFE, EFFECTIVE**
- * **QUEENSLAND SCIENTISTS STOP DENGUE WITH WOLBACHIA**
- * **AVEXA, PX BIOSOLUTIONS WIN VICTORIA TECHNOLOGY VOUCHERS**
- * **US PATENT FOR ATCOR CARDIAC OUTPUT METHOD**
- * **ANALYTICA REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.6 percent on Wednesday April 16, 2014 with the S&P ASX 200 up 32.1 points to 5,420.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and three were untraded. All three Big Caps were up.

Anteo was the best, up two cents or 12.5 percent to 18 cents with 8.5 million shares traded, followed by GI Dynamics up 12.15 percent to 60 cents with 1.4 million shares traded and Antisense up 10.3 percent to 16 cents with 95,026 shares traded.

Reva climbed 7.1 percent; Atcor was up 4.55 percent; Resmed rose 3.5 percent; Benitec, Bionomics, Patrys, Prana and Sirtex were up more than two percent; Cochlear, Nanosonics and Universal Biosensors were up one percent or more; with Acrux, CSL and Mesoblast up by less than one percent.

Circadian led the falls, down two cents or 10.5 percent to 17 cents with 27,275 shares traded.

QRX lost 7.3 percent; Living Cell fell 5.4 percent; Compumedics, Impedimed and Oncosil were down more than four percent; Admedus, Avita, Neuren and Osprey were down more than three percent; Prima and Starpharma shed more than two percent; with Alchemia down one percent.

ORTHOCELL

The Perth, Western Australia-based Orthocell hopes to have an initial public offer and list on the ASX to develop its tendon, cartilage and other regenerative medicine products. Orthocell managing director Paul Anderson told Biotech Daily that the company had Australian Therapeutic Goods Administration approval for its autologous, or patient's own, chondrocytes and tenocytes processes.

Mr Anderson said that Orthocell was in the process of applying for TGA approval for the pig-derived collagen scaffold.

Mr Anderson said 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.

Mr Anderson said that Orthocell was founded in 2006, based on technology developed at the University of Western Australia and so far more than 400 patients had been treated with the tendon and cartilage repair processes.

Mr Anderson said that healthy tendon tissue was harvested from the patient, processed to isolate tenocytes and injected into the damaged tendon.

He said that for cartilage repair the collagen scaffold was impregnated with similarly harvested and treated chondrocytes from the patient's healthy cartilage and the scaffold cut to the size and shape of the damaged cartilage and surgically implanted.

Mr Anderson said that a 25-patient phase I/II trial of Ortho-ATI for tennis elbow had been conducted at Perth's Sir Charles Gardiner Hospital and the results published in the American Journal of Sports Medicine in an article entitled 'Autologous Tenocyte Injection for the Treatment of Severe, Chronic Resistant Lateral Epicondylitis'.

An abstract is at: <http://www.ncbi.nlm.nih.gov/pubmed/24068695>.

He said that a 90-patient, randomized, controlled, double-blind phase II trial of Ortho-ATI had been completed at the Rotterdam, Netherlands-based Erasmus University, with results due by the end of 2014.

Mr Anderson said that the pig-derived collagen scaffold could be produced as an acellular sheet of scaffold from 50 microns to 350 microns.

He said the scaffold was initially created for the autologous chondrocyte implants but was found to have a number of attributes including that it was "very cell friendly with cells laying down their own matrix" on the scaffold.

Mr Anderson said the scaffold was strong and surgically compliant with anti-adhesion properties and haemostatic properties.

"The scaffold itself has properties beyond cell transplantation," Mr Anderson said.

Mr Anderson said that Orthocell was generating revenue from both the tendon and cartilage repair treatments.

Mr Anderson said that technologies' inventor, University of Western Australia orthopaedic surgery research director Prof Ming Hao Zheng, was Orthocell's chief scientific officer.

He said the company chairman was Bioscience Managers investment director, Dr Stewart Washer, who was also Cynata's chairman and formerly Phylogica and Calzada chief executive officer as well as the former chairman of Isona, Resonance Health and Hatchtech.

Mr Anderson said that Stone Ridge Ventures investment director Matt Callahan was also a director and was a founding director of Dimerix Bioscience.

Mr Anderson said the head of orthopaedics at Sweden's Lund University Prof Lars Lidgren and the Shenzhen, China-based Qi Xiao Zhou were also directors.

DRAWBRIDGE PHARMACEUTICALS

Drawbridge says that its 24-patient phase I dose-ranging trial of Phaxan has shown the anaesthetic to be safe and effective.

Drawbridge said that the trial showed Phaxan or alphaxalone dissolved in sulfobutyl ether beta cyclodextrin to be an effective fast-onset short acting intravenous anaesthetic equal to propofol, with a greater safety profile than propofol and causing less depression of blood pressure and respiratory control compared with propofol (BD: Dec 16, 2013).

The company said that the randomized, double-blind, dose-finding study compared the anaesthetic properties of Phaxan to propofol, the current gold standard for intravenous anaesthesia.

Drawbridge chief executive officer Dr Anthony Filippis told Biotech Daily that all the results for Phaxan were “statistically significant”, but said the company was unable to provide details until they were published in a peer-reviewed journal.

Drawbridge said the trial was conducted at Melbourne’s Jessie McPherson Private Hospital in 24 healthy male volunteers, with the Monash Health anaesthesia director Dr John Monagle as principal investigator.

The company said the for 90 minutes after drug injection as a single bolus dose it measured blood pressure, bispectral index, oxygen saturation, need for airway and ventilatory support, pain on injection, involuntary movement, nausea and measures of recovery, with arterial blood samples taken for routine analysis and measurement of complement fractions, C3 and C4.

Drawbridge said that Phaxan caused no pain on injection, while propofol caused pain and discomfort on injection in more than 50 percent of subjects, Phaxan caused no nausea and involuntary muscle movements occurred only in the propofol treated group.

The company said that cognitive function was preserved after Phaxan anaesthesia significantly better than with propofol and Phaxan caused no change in complement C3 and C4 levels.

Drawbridge chief medical officer Prof Colin Goodchild said the results from the first study in humans comparing Phaxan and propofol “clearly confirm all of the preclinical results ... [and] confirms that Phaxan is as fast as propofol in onset and offset of intravenous anaesthesia with improved cardiovascular and respiratory safety”.

“We are also pleased to report that the results clearly show that Phaxan administration was followed by a fast, clear-headed recovery characterized by significantly better cognitive function than after propofol,” Prof Goodchild said.

Drawbridge said it had “a robust patent portfolio” around Phaxan in the UK, Australia, New Zealand, Hong Kong, Singapore and South Africa with coverage to 2031.

“This study clearly shows that Phaxan has the clinical capacity to replace propofol as the drug of choice for intravenous anaesthesia, preclinical sedation and sedation in the [intensive care unit],” Dr Filippis said.

“Drawbridge is now engaged in active discussions with potential partners regarding the further development of Phaxan,” Dr Filippis said.

“We are confident that Phaxan will be successfully commercialized in the near future,” Dr Filippis said.

Drawbridge said that Phaxan was a water-based preparation making it easy to administer and eliminating the contamination issues of lipid-based propofol.

Drawbridge is a private company.

QUEENSLAND GOVERNMENT, JAMES COOK UNIVERSITY

The Queensland Government says that James Cook University scientists are closer to eradicating Dengue after field trials limited the spread of the disease.

A media release from Queensland Science Minister Ian Walker said researchers at the Cairns-based James Cook University had bred mosquitoes with the Wolbachia bacteria, which they demonstrated stopped mosquitoes transmitting the Dengue virus and then released the mosquitoes at trial sites to breed with wild mosquitoes that passed Wolbachia to their offspring.

"In the most recent outbreaks in Cairns, there was no evidence of local Dengue transmission in areas where mosquitoes infected with Wolbachia bacteria were released to breed with wild mosquitoes," Mr Walker said.

"We may not be able to claim it as a cure-all yet, but this research takes us a step closer to controlling this disease," Mr Walker said.

Mr Walker said Dengue was one of the most prevalent mosquito-borne viral diseases worldwide with up to 390 million people infected every year and 2.5 billion people at risk of the debilitating and sometimes deadly disease.

Mr Walker said the Eliminate Dengue Program was partially funded by the Queensland Government with \$1.95 million and showed promise for the Wolbachia method to provide a low-cost, self-sustaining and environmentally sound way to control Dengue fever.

"The results are informing Wolbachia trials in Indonesia and Vietnam, and there are plans for similar programs in Brazil, China and Colombia," Mr Walker said.

James Cook University's Prof Scott Ritchie said field trials with Wolbachia-infected mosquitoes began in 2011.

"Close to 100 per cent of mosquitoes in those sites are now carrying Wolbachia," Prof Ritchie said.

"In the past two years we have released Wolbachia mosquitoes in a further five sites in Cairns and the good news is that we're seeing no evidence of local Dengue transmission in all our release sites," Prof Ritchie said.

"We have shown that the Wolbachia bacteria stops the mosquito from being able to transmit the Dengue virus," Prof Ritchie said.

"The mosquitoes we rear are released to breed with wild mosquitoes and then Wolbachia is passed to the offspring," Prof Ritchie said.

For more information on the Eliminate Dengue program go to www.eliminatedengue.com.

VICTORIA GOVERNMENT, AVEXA

The Victoria Government says 13 companies will receive Technology Vouchers worth a total of over \$550,000 to develop new and improved products, services and processes. Victoria Minister for Technology Gordon Rich-Phillips said the \$8 million Technology Voucher Program supported projects that involve the development of new technologies or exploring the application of existing technologies in innovative or novel ways.

"As part of the Technology Voucher Program, we have also established a searchable directory of Technology Capabilities and Suppliers, listing companies and organizations that can provide services to voucher applicants," Mr Rich-Phillips said.

The Government said that the two biotechnology companies receiving vouchers were Avexa to investigate an improved, more cost-effective method for further development of two potential anti-HIV drugs and PX Biosolutions to assist in scale-up to manufacture a novel nanoparticle-based vaccine for gynaecological cancers.

For more information visit www.business.vic.gov.au/tvp.

Avexa was unchanged at 1.6 cents.

ATCOR MEDICAL

Atcor says the US Patent and Trademark Office has granted a patent entitled 'Method for determination of cardiac output' providing coverage until August 2026.

Atcor said the patent established a proprietary position in deriving cardiac output from the central aortic pressure waveform.

The company said that cardiac output was a measure of the volume of blood ejected by the heart into the cardiovascular system and was an indicator of sudden haemodynamic changes which might influence patient management and outcome especially in intensive care.

Atcor said it had begun a clinical trial for further evaluation of the cardiac output method of determination, prior to commercialization.

The company said it had seven patents covering multiple geographic jurisdictions and two more patent applications were in process.

Atcor has developed the Sphygmocor non-invasive measure of central aortic blood pressures and arterial stiffness.

Atcor was up half a cent or 4.55 percent to 11.5 cents.

ANALYTICA

Analytica has requested a trading halt "pending an announcement by the company of a capital raising".

Trading will resume on April 22, 2014 or on an earlier announcement.

Analytica last traded at 2.9 cents.