

Biotech Daily

Wednesday June 8, 2016

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: ANTISENSE UP 5%; LIVING CELL DOWN 11%
- * ALLEGRA BACK WITH BIORESORBABLE SR-HT-GAHNITE CERAMIC BONE
- * AIRXPANDERS RAISES \$20m, APPOINTS SCOTT MURCRAY CFO, COO
- * USCOM PLACEMENT RAISES \$2m
- * COMPUMEDICS \$700k CHINA ORDER; APPOINTS STEVE OTTO FOR SALES
- * OVENTUS LODGES \$12m IPO PROSPECTUS
- * ACTINOGEN: 'FDA ENHANCES PHASE II XANAMEM ALZHEIMER'S TRIAL'
- * NUHEARA SIGNS FLEXTRONICS FOR IQBUD MANUFACTURE
- * GENEVA UNI LETS EUROGOLD COMPLETE BARD 1 ACQUISITION
- * BIO-MELBOURNE: 'BIO-TECH HYPE LESSONS FROM THERANOS'
- * CRYOSITE APPOINTS ANDREW SHINE CEO
- * TREVOR DOOLAN REPLACES ITL CFO DAVID HOLDEN

MARKET REPORT

The Australian stock market slipped 0.02 percent on Wednesday June 8, 2016 with the ASX200 down 1.0 points to 5,370.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and four were untraded.

Antisense was the best, up 0.2 cents or 5.1 percent to 4.1 cents with 202,210 shares traded. Actinogen, Prana and Uscom climbed more than four percent; Neuren was up 3.45 percent; Impedimed, Medical Developments, Pro Medicus, Starpharma and Universal Biosensors rose one percent or more; with CSL and Nanosonics up by less than one percent.

Yesterday's best, Living Cell led the falls, retreating 0.7 cents or 10.8 percent to 5.8 cents with 3.7 million shares traded. Biotron lost 7.35 percent; Airxpanders, Bionomics and Cellmid fell four percent or more; Admedus, Anteo, Benitec, Clinuvel and Prima shed more than two percent; Acrux, Ellex, IDT, Orthocell, Polynovo and Viralytics were down more than one percent; with Cochlear, Reva, Resmed and Sirtex down by less than one percent.

ALLEGRA ORTHOPAEDICS

Allegra says a collaboration with the University of Sydney has developed a ceramic scaffold to assist regenerate bone tissue and degrade as it is replaced by natural bone. Allegra said that University of Sydney professor of bio-medical engineering Prof Hala Zreiqat and her team used three-dimensional printing technology to developed the ceramic, composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite (a zinc-aluminium-oxide), described as Sr-HT-gahnite.

"It actually kick-starts the process of bone regeneration making it a superior material to those bone substitutes currently available," Prof Zreiqat said.

"Our tests also show that it will not be rejected by the body," Prof Zreiqat said.

The company said that three-month histology results from sheep showed that the scaffold implants maintained their structure and were well tolerated with no evidence of adverse tissue reactions.

Allegra said that all the samples showed extensive bone in-growth which was integrated with bone at the defect edge and complete bridging of the defect was observed in some specimens.

The company said that the results were "promising and on-going bone formation was evident in all the samples".

Allegra said that the 12-month sheep study would be concluded "towards the end of 2016" and evaluation should show significantly greater bone in-growth and bridging of the defect. The company said it had appointed Ameneh Sadeghpour as project manager, effective from June 14, 2016, to coordinate with the University of Sydney's Tissue Engineering and Biomaterials Research Unit.

Allegra said Ms Sadeghpour held a Masters of Biomedical Engineering from the University of New South Wales, a Masters of Engineering from the University of Sydney and had experience in the pharmaceutical and medical device industries.

Allegra said that Prof Zreiqat's work on the ceramic Sr-HT-gahnite bone substitute won the \$US31,000 (\$A41,627) 2016-'17 Cambridge, Massachusetts-based Harvard University Radcliffe Institute Fellowship.

"Each patient has only a limited amount of bone available for grafting so the demand for synthetic bone substitutes is high [and] those currently available are far from optimal." "My work aims to change that," Prof Zreiqat said.

"This material has the potential to positively affect the quality of life of millions of people, so we are hoping to see it used clinically within the next five years," Prof Zreiqat said. Allegra listed on the ASX in December 2007 as Advanced Surgical Design & Manufacture to commercialize orthopaedic accessories and surgical tools including its own Total Knee, a hip cup for hip replacements and a Peripheral Access Device to increase the blood flow in legs to prevent amputation (BD: Feb 1, May 21, 2008).

In 2012, founder Dr Greg Roger was replaced as chief executive officer by the chief financial officer Tom Milicevic and the company announced distribution contracts with orthopaedic equipment suppliers, reporting revenue of \$7,175,000 for the year to June 30, 2013, \$7,972,000 for the year to June 30, 2014 and \$7,326,925 for the year to June 30, 2015 (BD: Mar 26, 2012; Sep 2, 2013; Sep 1, 2014; Aug 28, 2015).

In 2014, Mr Milicevic said the company had licenced the Sr-HT-gahnite composite from the University of Sydney for veterinary and orthopaedic indications and later its name to Allegra Orthopaedics (BD: Apr 2, Nov 28, 2014).

In 2015, Mr Milicevic resigned taking up the chief financial officer position at Oncosil and in April year, former sales manager Jenny Swain was appointed chief executive officer, having joined the company in 2010 (BD: Sep 29, Oct 22, 2015; Apr 21, 2016). Allegra climbed two cents or 13.3 percent to 17 cents.

AIRXPANDERS

Airxpanders says it has commitments to raise \$20,000,000 through subscriptions for 26,315,790 Chess depositary interests at 76 cents per CDI.

Airxpanders said that the placement to sophisticated and professional investors "was significantly oversubscribed, with strong demand from existing and new institutional funds, both domestically and overseas".

The company said that the funds would be used to increase Aeroform breast implant sales in Australia, sales and marketing investment for a US launch of Aeroform by April 2017, pending US Food and Drug Administration clearance, completion of commercial manufacturing transfer to Costa Rica and general working capital.

Airxpanders said that Canaccord Genuity Australia was the placement sole lead manager. The company said it had appointed Scott Murcray as chief financial officer and chief operating officer, effective from June 6, 2016.

Airxpanders said that Mr Murcray had more than 20 years financial experience and previously held finance and management roles at Nanometrics Inc and Zoll Medical Corp. The company said that Mr Murcray held a Bachelor's of Business Administration from California Polytechnic State University.

Airxpanders fell four cents or 4.5 percent to 85 cents.

USCOM

Uscom says it has raised \$2,2114,425 in an oversubscribed private placement at 20 cents a share.

Uscom said that the placement was "to accommodate strategic international investment and grow the corporate register".

The company said that the funds would be used to complete the Thor Laboratories acquisition, prepare and file regulatory approvals in China, Europe and the US, launch products and support a transition to volume manufacturing.

Uscom was up one cent or 4.35 percent to 24 cents.

COMPUMEDICS

Compumedics says it has received \$700,000 in orders for its diagnostic ultrasound products for brain blood flow monitoring from its China distributor.

Compumedics said that the order to its Germany subsidiary Compumedics Germany GmbH, formerly DWL Elektronische Systeme GmbH "confirms the on-going importance of the China market to the Compumedics Group with DWL having grown its business in China by more than 15 percent per annum over the past three-year period".

Compumedics executive chairman Dr David Burton said the company had "a significant presence in China and ... [was] the number one supplier of premium sleep diagnostic and neurological research systems in China and is carving out a similar position in [transcranial Doppler sonography] systems".

Compumedics said it had appointed Steve Otto to expedite the commercialization of its Curry magneto-encephalography (MEG) technology.

The company said Mr Otto was previously chairman and chief operating officer of the Stockholm, Sweden-based Elekta Neuromag, the dominant supplier to the MEG market. Compumedics said that the Curry MEG technology was a combination of its existing brain analysis software and the Korean Research Institute of Standards and Science's magneto-encephalography hardware.

Compumedics was unchanged at 40 cents.

OVENTUS MEDICAL

Oventus has lodged its prospectus with ASIC to raise up to \$12 million at 50 cents a share to list on the ASX to commercialize its O2vent anti-snoring mouth guard device. In April, Oventus said it hoped to raise \$15 million to \$20 million in the initial public offer (BD: Apr 6, 2016).

Today, the company said that the offer was fully underwritten by Bell Potter Securities and following the \$12 million capital raising it would be valued at \$36 million.

Oventus said the offer would open on June 16 and close on June 30, 2016.

The company said it had US Food and Drug Administration clearance for its O2vent device, formerly the Oventus Clearway Device, which had Australian Therapeutic Goods Administration approval and was available in Australia.

Oventus said that the device was intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnoea in patients unable to be helped with existing treatments including nasal obstructers and those who could not tolerate continuous positive airways pressure (CPAP) devices, such as Resmed-type face masks.

The company said its chairman was Dr Mel Bridges, with co-founder Neil Anderson appointed chief executive officer in 2014 and device inventor Dr Chris Hart its clinical director, with Sue MacLeman as an independent, non-executive director.

Oventus said that the three-dimensional-printed titanium mandibular, or jaw, advancement device fitted in a patient's mouth and had an airway that directed air to the back of the throat, bypassing nasal, soft palate and tongue obstructions.

The company said that a clinical study showed the O2vent was "successful in treating [obstructive sleep apnoea] and that snoring was either eliminated or significantly reduced in 100 percent of patients".

The prospectus is available at: www.oventusmedicalinvestors.com.

ACTINOGEN MEDICAL

Actinogen says it that discussions with the US Food and Drug Administration has led to an "enhanced protocol" for its phase II trial of Xanamem for Alzheimer's disease.

Actinogen said that FDA discussions were intended "to enhance the safety profile" of the 'Xanadu' trial.

The company said that it had made "good progress ... towards securing final US FDA approval" under an investigational new drug application.

Actinogen said that the enhanced protocol would be harmonized with both Australian and UK regulators and hospital sites, with patients expected to be enrolled by the end of 2016. The company said that a US-focused study and protocol design would "allow for broader value creation, as the US is the largest market for Alzheimer's drugs".

Actinogen was up 0.4 cents or 4.65 percent to nine cents with 2.5 million shares traded.

NUHEARA

Nuheara says it has a manufacturing agreement with the Singapore-based Flextronics to manufacture its Iqbuds sound filtering and device ear buds and related accessories. Nuhear said that Flextronics designed, built, shipped and serviced packaged consumer and industrial products, providing services through more than 100 facilities in 30 countries. Nuheara chief executive officer Justin Miller said pre-production services had begun, including the manufacture of tooling, development of production test equipment, pilot production runs, reliability testing and pre-compliance testing.

Nuheara fell 0.3 cents or 3.3 percent to 8.8 cents with 23.9 million shares traded.

EUROGOLD

Eurogold says a signed restriction agreement from the University of Geneva has been received and it can complete the acquisition of Bard1 AG and relist on the ASX. In March, Eurogold filed its prospectus to raise \$3 million at two cents a share for the acquisition of Bard1 AG to develop a blood test for cancer (BD: Mar 24, 2016). In December 2015 and February 2016 the Western Australian gold mining company said it hoped to acquire the Swiss public company, founded in 2011 by the University Hospital of Geneva's the head of the molecular gynaecology and obstetrics laboratory Dr Irmgard Irminger-Finger (BD: Feb 24, 2016).

The company said at that time that Bard1 AG had developed "a simple blood test for screening and diagnosing lung cancer at early stages of disease progression". Eurogold said that the lead manager for the offer was the Perth, Western Australia-based State One Equities.

The prospectus is available through the ASX platform under the company's EUG code. Eurogold was suspended at three cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that with Phillips Ormonde Fitzpatrick will host a Bio-Briefing entitled 'Bio-Tech Hype - Lessons from Theranos' on July 5, 2016.

The Network said the Palo Alto, California-based health-technology start-up was once a heralded company and is now under criminal investigation and facing a class action over its Edison method of blood-testing.

The Network said that the Bio-Briefing would discuss the implications of the Theranos case for in-vitro diagnostics, personalized medicine and disruptive healthcare technology. Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "there is also great interest in the legacy of the Theranos story on the regulatory, governance and the investor landscape for health-care start-ups and the broader industry".

The Network said that Bio-Briefing would have a panel discussion with Universal Biosensors chief scientific officer Dr Alastair Hodges and business development manager Pierre Nathie, LBT chief executive officer Lusia Guthrie and Theranos former vice-president of human health products David Lester.

The Bio-Briefing will be held at the offices of Philips Ormonde Fitzpatrick, 333 Collins Street, Melbourne on July 5, 2016.

Registration is from 3:45pm with the panel discussion from 4pm to 5.30pm followed by a networking session.

To register go to: http://biomelbourne.org/event/healthtech-hype-lessons-theranos/.

CRYOSITE

Cryosite says it has appointed Andrew Shine as chief executive officer effective from June 14, 2016.

Cryosite said that Mr Shine had worked with Monash IVF, Icon Cancer Care, Virtus Health in Australia and Trinity Biotech in the UK.

The company said that Mr Shine's remuneration package including superannuation would be \$220,000 and he would be eligible for short and long term incentives.

Cryosite thanked Graeme Moore for his efforts as interim chief executive officer since September 2015 and would revert to his previous position as operations executive director.

Cryosite was untraded at 18.5 cents.

<u>ITL</u>

ITL says that chief financial officer David Holden will retire on June 30, 2016 having led the company's finance team for the last six years.

ITL said that financial controller Trevor Doolan would replace Mr Holden as chief financial officer and Mr Holden had agreed to continue as a consultant for special projects. The company said that Mr Doolan had been group and Australia healthcare financial controller and company secretary for more than five years.

ITL was up one cent or 6.25 percent to 17 cents.