



Biotech Daily

Monday May 6, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ANTEO UP 20%, ATCOR DOWN 11%**
- * **NANOSONICS STUDY SHOWS TROPHON CLEARS ALL BACTERIA**
- * **PRANA'S \$2m SHARE PLAN TAKES TOTAL TO \$7m**
- * **BPH, CORTICAL DYNAMICS: 'BRAIN MONITOR MEASURES DRUG DOSES'**
- * **CLINUVEL PLACEMENT RAISES \$6.3m**
- * **GENETIC TECHNOLOGIES, LABORATORY CORP LICENCE**
- * **CELLMID REQUESTS ACQUISITION TRADING HALT**
- * **AUSTRALIAN ETHICAL TAKES 5% OF PHARMAXIS**
- * **DR GREG COLLIER REPLACES INVION CEO DR WILLIAM GARNER**
- * **BIONICHE REFUSES 'INVALID' DISSIDENT EGM REQUEST**

MARKET REPORT

The Australian stock market climbed 0.52 percent on Monday May 6, 2013, with the S&P ASX 200 up 26.7 points to 5,156.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 10 traded unchanged and six were untraded.

Anteo was the best, up 1.1 cents or 20.4 percent to 6.5 cents, with 4.85 million shares traded, followed by Clinuvel up 13.5 percent to \$2.10 with 14,964 shares traded.

Psivida climbed 9.4 percent; Prima was up 8.3 percent; QRX was up 7.8 percent; Allied Health and Universal Biosensors were up more than three percent; Avita, Genetic Technologies and Prana rose more than two percent; Cochlear and Starpharma were up one percent or more; with Mesoblast and Sirtex up by less than one percent.

Atcor led the falls, down 0.9 cents or 11.0 percent to 7.3 cents with 125,000 shares traded.

Antisense and GI Dynamics lost nine percent or more; Patrys and Tissue Therapies were down more than seven percent; Heartware fell four percent; Bionomics and Neuren shed more than two percent; Alchemia, Nanosonics and Viralytics were down more than one percent; with CSL and Resmed down by less than one percent.

NANOSONICS

Nanosonics says a Melbourne study has shown that its Trophon EPR decontaminated ultrasound probes clear all bacteria, while manual decontamination does not.

The company said that a study entitled 'Clinical comparison of high level disinfection techniques for reprocessing trans-vaginal ultrasound probes' by East Melbourne Ultrasound Clinic obstetrician and gynaecologist Dr Andrew Ngu, partly funded by Nanosonics, was presented at the World Federation for Ultrasound in Medicine and Biology conference in Sao Paulo Brazil on May 3, 2103.

Nanosonics said study compared the standard process for manual decontamination, which involved soaking the probe in a liquid disinfectant against its Trophon EPR automated unit and checked for bacteria on the handles of the probes after decontamination.

Dr Ngu's study found that 96 percent of 51 swab samples collected from manually decontaminated probes showed signs of bacteria on the handle after the disinfection process, compared to no bacterial contamination on 42 swabs taken from handles of probes decontaminated using the Trophon EPR unit ($p < 0.05$).

Dr Ngu said a major factor was manufacturer advice which prevented the probes from being fully submerged in the liquid disinfectant (Cidex OPA) used in the manual process.

"The inability to fully submerge these probes in the liquid disinfectant creates a safe haven for bacteria on the handle," Dr Ngu said.

"We found large quantities of bacteria on most handles when probes were reprocessed this way and this was not an entirely unexpected result," Dr Ngu said.

"While it is important to note these probes are used with a protective sheath and the handle does not enter the body, the presence of bacteria on a medical device does pose a risk of cross-infection for patients," Dr Ngu said.

Nanosonics said the study concluded with a call for stricter disinfection standards which required use of devices, such as the Trophon EPR, or techniques that ensured high-level disinfection of the entire probe including its handle.

Nanosonics chief executive officer Dr Ron Weinberger said the research was further validation of the superior results achieved through the use of Trophon EPR, which encases and disinfects the entire probe.

Nanosonics said that hospital acquired infections cost the US health system an estimated \$US35 billion a year and at least one in 20 Australian patients would acquire an infection in hospital, equating to about 180,000 infections a year and two million extra bed days.

The company said that infections could be spread by poor personal hygiene, but even more alarming infections are sometime caused by medical equipment that has already been disinfected.

Nanosonics fell half a cent or 1.2 percent to 40 cents.

PRANA BIOTECHNOLOGY

Prana says its underwritten share plan has raised \$2,022,245 through the issue of 10,370,488 shares at 19.5 cents a share, taking the total raised to \$7,022,245.

In March, Prana said it raised \$5 million in a placement at 19.5 cents a share to Australian institutions and high net worth investors and expected to raise a further \$2 million through an underwritten share purchase plan, managed by Melbourne's JM Financial Group, which would underwrite the share plan (BD: Mar 28, 2013).

Prana said that the funds would be used to advance development of PBT2 which was in two concurrent phase II clinical trials in Huntington disease and Alzheimer's disease.

Prana was up half a cent or 2.4 percent to 21 cents.

BPH ENERGY CORTICAL DYNAMICS

BPH Energy says a study of three percent investee company Cortical Dynamics' brain anaesthesia monitor shows it can distinguish between low and moderate doses of fentanyl. The study of 25 patients entitled 'Validation of the Brain Anaesthesia Response Monitor During Anaesthesia for Cardiac Surgery: a Double-Blinded Randomized Controlled Trial Using Two Different Doses of Fentanyl' and conducted at Melbourne's St Vincent's Hospital concluded that "the ability of the cortical input (CI) index to differentiate the two groups by fentanyl dose indicates that the BAR Monitor may be useful in the titration of fentanyl as an anti-nociceptive agent during cardiac surgery".

BPH said the results were presented at the Australian and New Zealand College of Anaesthetists meeting in Melbourne on May 4, 2013.

The study poster said patients undergoing elective coronary artery bypass surgery were randomized to 12 microgram/kg or 24 microgram/kg of fentanyl.

BPH said the study was designed to evaluate the ability of the brain anaesthesia response (BAR) monitor to distinguish between two different doses of the widely used intravenous analgesic as well as assess the immunity of the BAR monitor to a range of intra-operative mechanical and electrical artifacts known to complicate the electroencephalogram (EEG) measurement of anaesthetic action.

BPH said the principle investigator was St Vincent's Hospital senior staff anaesthetist Dr Desmond McGlade.

The presentation said that 20 patients were evaluable and the relative change in cortical input was greater in the low dose than the moderate dose ($p = 0.004$).

The company said that in contrast, the BAR monitor's cortical state index and the simultaneously recorded bispectral index were unchanged.

BPH said the ability of the CI index to distinguish between the two different fentanyl doses indicates that the BAR monitor may be useful for the intra-operative monitoring of analgesia and that, given that during this study the cortical state index was highly correlated with the bispectral index, it suggested that the BAR monitor could find use in the delivery of optimal and balanced surgical anaesthesia.

BPH and Cortical chairman David Breeze said the study showed that the BAR monitor had features and sensitivities that existing market leading products did not have.

"This is an exciting result as it shows, on the basis of an independent clinical trial, that the BAR monitor has features and sensitivities that existing market leading products do not possess," Mr Breeze told Biotech Daily.

"Our monitor has been shown to detect the different doses of fentanyl, something no existing EEG-based monitor can do," Mr Breeze said.

"The fact that we are able to present this important result at the ANZCA meeting means we can immediately discuss ways in which the BAR monitor can best be integrated into existing clinical practice," Mr Breeze said.

BPH said the BAR Monitor measures electroencephalograms via an adhesive sensor applied to the forehead to indicate how deeply anaesthetized a patient was during an operation.

The company said the monitor improved on currently used electroencephalogram (EEG) monitors by using a physiological approach aimed at independently monitoring the hypnotic and analgesic states associated with anaesthesia, a feature no known existing EEG based monitor was able to achieve.

BPH Energy fell 0.1 cents or 5.6 percent to 1.7 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has raised \$6.3 million in a placement to institutional and professional investors at \$2.136 a share.

Clinuvel said the price was a 4.3 premium to the 20-day volume weighted average price on April 29 and a 15.1 percent premium to the closing price on April 30, 2013.

The company said that the funds would be used for an expanded global clinical trial program of Scensse (afamelanotide 16mg implant) in patients with the pigmentary disorder vitiligo and to file a new drug application to the US Food and Drug Administration and to cover operating and commercialization costs while awaiting a decision from the European Medicines Agency on its application for marketing authorisation (MAA) for the orphan indication erythropoietic protoporphyria, expected by the end of 2013.

Clinuvel chairman Stan McLiesh said the funds gave the company “the ability to proceed with larger vitiligo trials, with a phase IIb [trial] to commence in 2013, and pursue the [erythropoietic protoporphyria] program in the US, while we are awaiting the EMA outcome”.

Clinuvel was up 25 cents or 13.5 percent to \$2.10.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a licence agreement with Laboratory Corporation of America arising from an agreement originally granted to Genzyme Corp in 2004.

Genetic Technologies said that under the original agreement, it was to be paid, partly in cash and partly in-kind by Genzyme but the amount was not fully received at that time, resulting in an arbitration initiated against Genzyme.

The company said that subsequently, the agreement with Genzyme was transferred to the Burlington, North Carolina-based Laboratory Corp.

Genetic Technologies said it recently met with Laboratory Corp in New York under the supervision of an independent mediator and a complete settlement was achieved.

The company said that the precise terms of the agreement were covered by confidentiality provisions.

Genetic Technologies was up 0.2 cents or 2.5 percent to 8.2 cents.

CELLMID

Cellmid has requested a trading halt “in relation to a proposed acquisition that is material to the company’s business”.

Trading will resume on May 8, 2013 or on an earlier announcement.

Cellmid last traded at 2.5 cents.

PHARMAXIS

Australian Ethical Smaller Companies Trust has become a substantial shareholder in Pharmaxis with the acquisition of 15,448,517 shares (5.01%).

Australian Ethical’s substantial shareholder notice said it acquired shares between January 9 and May 1, 2013 with the largest acquisition, the most recent of 3,250,350 shares for \$536,853 or 15.25 cents a share.

Pharmaxis was unchanged at 15 cents with 1.8 million shares traded.

INVION (FORMERLY CBIO)

Invion has appointed former Chemgenex chief executive officer Dr Greg Collier managing director and chief executive officer replacing Dr William Garner.

Dr Garner was appointed chief executive officer last year when CBio merged with Dr Garner's Inverseon to become Invion (BD: Jul 2, Aug 30, 2012).

Invion said that Dr Collier would have a base salary of \$300,000 plus nine percent statutory superannuation and would be eligible to up to 30 percent of the base salary as a short term incentive, and a long term incentive through the employee share option plan, subject to shareholder approval.

The company said Dr Collier had more than 20 years experience spanning operational, clinical and scientific aspects of pharmaceutical research, development and commercialization and had led the planning and execution of multiple commercial transactions including in and out licencing deals and merger and acquisition activities, and had successfully taken a drug from discovery through to regulatory approval.

Invion said Dr Collier took Chemgenex Pharmaceuticals from a research-based company with a market capitalization of \$10 million to a company with completed clinical trials and regulatory dossiers submitted to the US Food and Drug Administration and European Medicines Authority and was sold to Cephalon for \$230 million in 2011 (BD: Dec 5, 2012).

The company said that prior to Chemgenex, Dr Collier had more than 150 peer-reviewed publications and senior authorship on 33 patents.

Invion said that Dr Collier had held positions at the University of Melbourne, Monash University, the University of Toronto and Deakin University.

The company said that Dr Garner would remain Invion's largest shareholder.

Invion chairman Dr Ralph Craven said Dr Garner facilitated the merger of Inverseon and CBio last year.

Invion fell 0.9 cents or 18 percent to 4.1 cents.

BIONICHE LIFE SCIENCES

Bioniche says the shareholder extraordinary general meeting request is invalid and it will not call a meeting as requested (BD: Apr 24, 29, 2013).

Bioniche said that with the advice of legal counsel it "has determined that the dissident shareholder's request for a shareholder meeting received on April 25, 2013 does not constitute a valid shareholder requisition" and would not call a meeting.

The dissident shareholders have said they represented a group of concerned investors holding more than five percent of the issued capital of Bioniche.

The company said the request was not valid as it was made by a beneficial shareholder whereas a requisition must be made by a registered shareholder and the request did not provide adequate information to permit shareholders to make a decision concerning the business in the letter and failed to provide the names of the individuals who were to be nominated or any other information about the proposed nominees.

It was not clear from either party whether the meeting request was being pursued under Canadian or Australian corporate law. Bioniche is listed on both the ASX and Toronto Stock Exchange.

Bioniche was untraded at 19 cents.