



Biotech Daily

Tuesday March 6, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP:**
 - **SUNSHINE HEART UP 15%, IMPEDIMED DOWN 6%**
- * **PRANA STARTS PHASE II PBT2 ALZHEIMER'S IMAGING TRIAL**
- * **ANTEO FILES MIX&GO US PATENT APPLICATION, 'IP STRENGTHENED'**
- * **PHOSPHAGENICS APPOINTS HUGH ALSOP VP OPERATIONS, BUSINESS**
- * **NUSEP SIGNS DISTRIBUTOR; ASIC RESERVES PENALTY RIGHTS**
- * **BIO-MELBOURNE BIO-INFORMATICS, IMAGING, MODELING BREAKFAST**
- * **KOREAN PATENTS FOR BONE MEDICAL'S AXCESS II, III**
- * **FLUOROTECHNICS TAKES 'GOING MINING' HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 1.37 percent on Tuesday March 6, 2012 with the S&P ASX 200 down 58.3 points to 4204.7 points.

Fifteen of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and seven were untraded. All three Big Caps fell.

Sunshine Heart was the best, up 0.7 cents or 14.9 percent to 5.4 cents with 6.6 million shares traded, followed by Bionomics up 8.7 percent to 50 cents with one million shares traded.

Genetic Technologies climbed five percent; Clinuvel and Neuren were up more than four percent; both Prana and QRX were up 3.2 percent; Phosphagenics, Phylogica and Prima rose more than two percent; Nanosonics and Viralytics were up more than one percent; with Acrux, Heartware and Sirtex up by less than one percent.

Impedimed led the falls, down three cents or 6.1 percent to 46.5 cents, with 52,472 shares traded.

Benitec lost 5.3 percent; Alchemia fell 3.45 percent; Avita and Mesoblast shed more than two percent; Biota, Living Cell, Pharmaxis and Resmed were down one percent or more; with Cochlear, CSL and Starpharma down by less than one percent.

PRANA BIOTECHNOLOGY

Prana says the first of up to 40 patients has been dosed in a 12-month, randomized, double-blind, placebo-controlled phase II imaging trial of PBT2 for Alzheimer's disease. Prana said the Melbourne-based study, to be known as the 'Imagine' trial, would assess the safety and tolerability of PBT2 and its effect on amyloid levels in the brains of patients with prodromal or mild Alzheimer's disease.

Trial details provided by Prana said that the primary outcome was to evaluate the effect of PBT2 compared to placebo on brain amyloid levels after 52 weeks of treatment as measured by carbon 11-Pittsburgh imaging compound-B (PiB) positron emission tomography (PET) imaging at 26 and 52 weeks after beginning treatment with PBT2 or the placebo.

The trial details are at: <http://www.anzctr.org.au/ACTRN12611001008910.aspx>.

The company said that secondary outcomes included the evaluation of the safety and tolerability of PBT2 compared to placebo as measured by capture of vital signs, physical examination, neurological examination, electro-cardiogram, eye examination, blood haematology and biochemistry, urinalysis and recording of adverse events.

The trial data said that from previous clinical trials, the most commonly reported side effects that were possibly related to PBT2 were fatigue, headache, dizziness, nasopharyngitis or swollen blocked nose and drowsiness.

The trial data said that less common side-effects possibly related to PBT2 were diarrhoea, back pain, nausea and throat pain and it was possible that a rare side effect could be dissociation or a feeling of disconnecting from one's thoughts, feelings, memories or self. Other secondary outcomes included evaluation of the effect of PBT2 compared to placebo on brain metabolic activity after 52 weeks as measured by fluorine 18 labeled fluorodeoxyglucose (FDG) PET imaging, along with evaluating the effect of PBT2 on brain volumes after 52 weeks as assessed by magnetic resonance imaging to measure the cortical grey matter volume, hippocampal volume and ventricular volume, as well as evaluating the effect of PBT2 on cognition as measured by a neuropsychological test battery questionnaires and the mini-mental state examination questionnaire and evaluating functional ability through an established questionnaire

Prana said that PBT2 significantly changed amyloid beta levels in spinal fluid and significantly improved the cognition of Alzheimer's disease patients in an earlier 12 week clinical trial and would be assessed in the 12 month study for its effects on the distribution of amyloid in the brain and cognitive and functional improvement (BD: Jul 30, 2008).

Prana executive chairman Geoffrey Kempler said the 12 month trial would establish PBT2's credentials as a safe and effective treatment for Alzheimer's disease.

The company said the received funding from the Alzheimer's Drug Discovery Foundation whose executive director Dr Howard Fillit said that PBT2 "stands out as one of the few remaining orally available agents with clinical trial evidence of cognitive benefit for Alzheimer's patients".

"Success in this trial will demonstrate target engagement by PBT2 in the brains of people with Alzheimer's disease and accelerate the clinical development of PBT2 to patients," Dr Fillit said.

Prana said that the data supporting the belief that PBT2 would bring meaningful clinical benefit to patients was extensive and PBT2 restored neuronal health by selectively binding and redistributing brain metals including copper and zinc that have become imbalanced due to disease or the ageing process.

The company said that PBT2 was able to prevent amyloid beta-induced toxicity and promote its disaggregation in the brain.

Prana was up half a cent or 3.2 percent to 16 cents.

ANTEO DIAGNOSTICS

Anteo says it filed a divisional patent entitled 'Use of Metal Complexes' for its Mix&Go technology with the US Patent and Trademark Office on March 2, 2012.

The company said the divisional filing followed the allowance of the parent 'Use of Metal Complexes' patent (BD: Jan 22, 2012).

The company said that the imminent grant of enforceable rights was expected on the parent patent, given that final formalities in the procedure were being completed by the USPTO.

Anteo said that it expected that execution of the patent strategy would provide for exclusivity to production of surfaces comprising Mix&Go, the Mix&Go coated surfaces and uses to which the surfaces can be put.

The company has previously said Mix&Go could be used to bind antibodies to more than 8,000 different types of surfaces and allowed proteins or biomarkers to be detected at lower concentrations and across a broader concentration range, with improved stability and reduced lot-to-lot variability (BD: Sep 12, 2011).

Today, Anteo said the divisional filing would provide greater flexibility in discussions with prospective licencees regarding coverage of patent protection and enhance the company's negotiating position.

The company said that IP Australia, the Australian patent office, had granted its application for the 'Use of Metal Complexes' patent for Mix&Go, along with the grant of the same patent in Japan and the grant of the 'Generation of Surface Coating Diversity' patent in Europe in September 2011.

Anteo said it was "very satisfied" with its dialogue with interested parties.

The company said it was in negotiations with a number of life sciences and in vitro diagnostic companies and "whilst this is a lengthy process that requires considerable patience, we remain optimistic that we will be able to update shareholders with developments in the near future".

Anteo chief executive officer Dr Geoff Cumming said that protecting the Mix&Go technology was "of critical importance for Anteo and the recent developments announced today are particularly pleasing".

"The application for a divisional patent in the US and the granting of the Australian patent ... provides us with enhanced security in the protection of our exciting technology and flexibility in our dealings with prospective partners," Dr Cumming said.

Anteo was unchanged at 7.6 cents with 4.7 million shares traded.

PHOSPHAGENICS

Phosphagenics has appointed Hugh Alsop as head of operations and business development, effective from March 5, 2012.

Mr Alsop told Biotech Daily that he was previously employed by Acrux in the team that commercialized the Axiron transdermal testosterone replacement therapy, launched in the US last year (BD: Mar 31, 2011) and would be heavily involved in Phosphagenics transdermal oxycodone program, which had "a very similar regulatory pathway" to Axiron. Mr Alsop said he had worked in the pharmaceutical industry for more than 15 years and prior to Acrux, was employed by Sigma Pharmaceuticals, and before that spent eight years with Faulding, which became Mayne Pharma, which was acquired by Hospira.

Mr Alsop holds a Bachelor of Science honors degree in chemistry from the University of Melbourne and a Master of Business Administration from the Melbourne Business School. Phosphagenics was up half a cent or 2.4 percent to 21.5 cents with three million shares traded.

NUSEP

Nusep says it has signed a distribution agreement with In Vitro Technologies for the sale of its consumable products in Australia and New Zealand.

Nusep said that In Vitro Technologies was a Melbourne-based scientific and medical distribution company specializing in the sale and support of scientific, clinical diagnostic, medical and related products, with offices throughout Australia and New Zealand.

The company said that In Vitro Technologies had a customer base in the protein expression and detection markets and Nusep Nuvue Gels range provide a natural complementary fit with their existing product ranges.

Nusep said the Australian analytical gel market was worth \$2.5 million a year.

Nusep managing director Dr Hari Nair said that "distribution is the key to expanding Nusep's sales".

"The ability to partner with a respected distributor means that Nusep will be able to expand its market penetration of its Nuvue gels in Australia," Dr Nair said.

Nusep said that in December 2011 it made the Australian Securities and Investments Commission aware of certain breaches of the Corporations Act (BD: Dec 12, 2011) and that ASIC had not indicated an intention to take any action in connection with the breaches.

Today Nusep said that while the earlier statement was "correct and no action has been taken by ASIC to date ... ASIC did advise ... that it reserves its rights to take action in relation to the contraventions".

Nusep fell 0.1 cents or 2.6 percent to 3.8 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's March 13 Bio-Breakfast will discuss the Victorian Life Sciences Computation Initiative, advances in bioinformatics and personalized medicine. The Bio-Melbourne Network said the Parkville-based, \$100 million Victorian Government initiative in partnership with the University of Melbourne and the IBM Life Sciences Research Collaboratory was launched in 2010 and was "an example of the convergence between the physical sciences, information technology and the biological sciences".

The Network said that the Initiative's head of life sciences computation centre, Prof Andrew Lonie would give an overview of the key research areas at facility, advances in bioinformatics capabilities and personalized medicine, including commercial perspectives and opportunities

The Network said that the Victorian Life Sciences Computation Initiative aimed to be a world leader in life science research in the key areas of computational biology, bioinformatics, and computational imaging and would be home to the world's greenest supercomputer, the IBM Blue Gene-Q hosted by the University of Melbourne.

The Network said that Monash Biomedical Imaging director Prof Gary Egan would discuss new biotechnology opportunities relating to the Victorian Biomedical Imaging Capability facilities, including new bio-imaging techniques for assessing experimental diagnostics such as neuro-degeneration and therapeutics including stem cells.

The Network said that Initiative's molecular modeling scientist Dr Michael Kuiper would present computer simulations demonstrating how drugs work and how this research helped identify target molecules for drug resistance.

The March 13, 2012 Bio-Breakfast will be held at the Australian Centre for the Moving Image, Federation Square, Melbourne, with registration from 7:15am, followed by the presentations at 8am.

For information or to book go to: <http://www.biomelbourne.org/events/view/219>.

BONE MEDICAL

Bone says it has received notice of allowance of two patent applications for its Axcress II and III oral peptide formulation technology in Korea.

Bone said it had an exclusive worldwide licence to the Axcress technology in its target disease fields from London-based Proxima Concepts.

Proxima's website says that Bone chairman Dr Roger New is the co-founder and research and development director of Proxima.

"The allowance of these two patents covers important elements of our Axcress oral peptide formulation technology in one of the most important Asian markets," Dr New said.

Bone was up 0.3 cents or 23.1 percent to 1.6 cents with 8.8 million shares traded.

FLUOROTECHNICS

Fluorotechnics has requested a voluntary suspension to follow the trading halt it requested on March 2, 2012, pending an announcement "regarding the option to acquire certain resource assets" (BD: Feb 13, Mar 2, 2012).

Fluorotechnics last traded at 1.6 cents.