Biotech Daily

Friday June 24, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AIRXPANDERS UP 8%; ORTHOCELL DOWN 12.5%**

*** UCLA BACKS GENETIC SIGNATURES ENTERIC PATHOGEN TEST**

*** BIONOMICS COMPLETES PHASE II BNC210 ANXIETY TRIAL ENROLMENT**

*** CELLMID: 'MIDKINE ANTIBODIES AID BONE HEALING IN MICE'**

*** MEDIBIO: 'ALGORITHM DISTINGUISHES FIVE SLEEP STAGES'**

*** CONTAGNO BACK-DOOR INTO TYRIAN FOR ASSET MANAGEMENT**

*** GAMEDAY + MT MAGNET SOUTH = IMPRESSION MOUTH GUARDS**

MARKET REPORT

The Australian stock market tumbled 3.17 percent, following the British vote to leave the EU on Friday June 24, 2016, with the ASX200 down 167.5 points to 5,113.2 points.

Just seven of the Biotech Daily Top 40 stocks were up, 28 fell, with five trading unchanged and all three Big Caps falling.

Airxpanders was the best, up seven cents or 7.95 percent to 95 cents with 1.1 million shares traded. Living Cell and Neuren climbed more than five percent; Factor Therapeutics rose 2.9 percent; with Bionomics, Clinuvel and Universal Biosensors up more than one percent.

Orthocell led the falls, down four cents or 12.5 percent to 28 cents with 553,769 shares traded, followed by Compumedics down 10.7 percent to 37.5 cents with 147,750 shares traded.

Anteo and IDT lost more than nine percent; Pharmaxis and Psivida fell more than seven percent; Antisense was down 6.1 percent; Admedus, Ellex, Genetic Technologies, Medical Developments, Nanosonics, Opthea and Viralytics fell five percent or more; Actinogen, Acrux, Mesoblast and Prima lost more than four percent; Atcor, Avita, Biotron, Impedimed, Starpharma and Uscom were down three percent or more; CSL, Prana and Pro Medicus shed two percent or more; Benitec and Sirtex were down more than one percent; with Cochlear and Resmed down by less than one percent.

GENETIC SIGNATURES

Genetic Signatures says a University of California, Los Angeles evaluation of its enteric pathogen test shows it is superior to traditional methods.

Genetic Signatures chief executive officer Dr John Melki told Biotech Daily that enteric pathogens caused gastroenteritis and diarrhoea and the company's 3-Base diagnostic identified protozoan targets including Blastocystis species (spp) and Dientamoeba fragilis.

In a media release, Dr Melki said the company would develop a process with UCLA that would see its products "adopted into routine use".

"This successful trial of our rapid pathogen screening assays represents a key milestone in the company's commercial rollout," Dr Melki said.

The head of UCLA clinical microbiology Dr Romney Humphries said the group was "very pleased with our study results and look forward to working with Genetic Signatures to focus on the best technologies to enhance patient care".

"We will soon be sharing our results in upcoming publications highlighting the infections that can be missed with traditional methods," Dr Humphries said

Dr Melki said the company sought the views of an independent key opinion leader and reported the former manager of the UCLA clinical microbiology laboratory Lynne Garcia saying that the company had "consulted with leading experts to develop an assay that identifies Blastocystis spp and Dientamoeba fragilis, both of which are potentially clinically significant pathogens".

"Based on advice from their panel of experts, Genetic Signatures will soon expand their assay to identify two Microsporidia, Enterocytozoon bieneusi and Encephalitozoon intestinalis," Ms Garcia said. "Inclusion of these pathogens will provide clinicians with valuable information to select a course of treatment and improve patient outcomes."

Genetic Signatures climbed five cents or 11.1 percent to 50 cents.

BIONOMICS

Bionomics says it has completed enrolment in its UK 24-patient phase II trial of BNC210 for generalised anxiety disorder.

Last year, Bionomics said the double-blinded, controlled, four-way crossover single-centre study would use functional magnetic resonance imaging to assess the effect of BNC210 on brain activity in patients with untreated generalized anxiety disorder, randomized to receive BNC210 300mg or 2000mg, placebo or 1.5mg lorazepam (BD: Apr 20, 2015).

The company said the study would evaluate the capacity of BNC210 to engage brain systems relevant to anxiety, with endpoints including significant changes in cerebral perfusion and in task-related brain activity with functional magnetic resonance imaging.

Bionomics said the study was being conducted by King's College London's Prof Allan Young as principal investigator.

Bionomics chief executive officer Dr Deborah Rathjen said that timely completion of enrolment was an important milestone for the trial with data expected by October 2016.

"Bionomics continues to focus on the discovery and development of innovative therapeutics such as BNC210, which we believe presents a significant opportunity to reduce the impact of anxiety both on sufferers and the wider community," Dr Rathjen said.

"BNC210 possesses significant potential in meeting a currently unmet medical need for fast-acting anxiolytic agents that do not carry the side-effects of existing treatments such as sedation, addiction and negative effects on memory and coordination," Dr Rathjen said.

Bionomics said it was initiating a phase II trial of BNC210 in post-traumatic stress disorder, expected to begin by July, 2016.

Bionomics was up half a cent or 1.7 percent to 30 cents.

CELLMID

Cellmid says a German collaboration has shown that treatment with a midkine antibody accelerated bone fracture healing in mice.

Cellmid said that the study, entitled 'Antagonizing Midkine Accelerates Fracture Healing in Mice by Enhanced Bone Formation in the Fracture Callus' was conducted at the Ulm, Germany-based University Medical Center Institute of Orthopedic Research and Biomechanics, led by Dr Astrid Liedert, and was published in the British Journal of Pharmacology, with an abstract at: http://www.ncbi.nlm.nih.gov/pubmed/27111560.

The article concluded that midkine antibody treatment "may be a potential novel therapeutic strategy to enhance fracture healing in patients with orthopaedic complications such as delayed healing or non-union formation".

Cellmid said that Dr Liedert discovered that midkine protein in blood levels increased dramatically following bone fractures, and with previous studies that showed how midkine controlled normal bone growth, implicating midkine in bone damage conditions.

The company said that after 10 days treatment, the amount of bone deposited in the fracture site was increased significantly ($p < 0.05$), while the mechanical strength of the bone and bone repair were markedly improved after 28 days of treatment ($p < 0.05$).

Cellmid said that detailed analysis of the bone fracture showed that the midkine protein accumulated within the healing bone and acted to slow the repair process.

The company said that midkine antibody treatment reduced the amount of midkine in the bone fracture site and diminished the amount circulating in the blood and that by reducing the availability of midkine in both healing bone and blood, the midkine antibody treatment led to faster bone replacement and better quality, stronger bone within the fracture.

The company said that Dr Liedert found that the midkine antibody impacted on the wingless-related integration site, or Wnt, signalling system that regulated bone formation, the target of drugs being developed for osteoporosis.

Cellmid said that demonstrating the beneficial effects of a midkine antibody in bone fracture healing had considerable clinical significance as the rate of delayed bone healing and non-union formation could be up to 10 percent of all long bone fractures, which increased among the older population.

The company said the data added commercial value to its antibody assets and the new intellectual property was the subject of a patent application.

Cellmid said it had promising data using its antibodies to antagonize midkine in chronic kidney disease models and with the bone fracture data would investigate whether midkine antibodies would be useful in preventing vascular calcification, a complication and major cause of death in patients with type 2 diabetes and chronic kidney disease.

The company said that the collaboration with Dr Liedert's group was "the direct outcome from the company's biennial midkine symposia", where Dr Liedert first presented preliminary results on midkine levels following bone fracture in 2014.

Cellmid said the bone fracture study was designed with Dr Liedert's group and the results were shared with the midkine community in the April 2016 symposium.

Cellmid head of research and development Prof Graham Robertson said that "while considerable preclinical and clinical development is still required to assess [midkine] antibodies as treatments for bone disorders, the current study by Dr Liedert demonstrates the potential of this approach".

Cellmid chief executive officer Maria Halasz said that "with our promising results in the treatment of chronic kidney disease, we are encouraged to investigate complex and unexplored major complications of diabetic nephropathy, such as vascular calcification leading to serious cardiovascular events".

Cellmid was unchanged at three cents with 8.8 million shares traded.

MEDIBIO

Medibio it has developed and validated an algorithm that uses electro-cardiogram data to distinguish the five sleep stages with accuracies of 86 percent to 95 percent.

Medibio said the accuracy compared “favourably to the numerous previous attempts by researchers to accurately determine the sleep stages using [electro-cardiogram] data alone”, with the best historical results in the 70 percent range for all five stages of sleep.

The company said that the project was part of its collaborative research and development effort with four US universities (BD: Mar 11, 2016).

Medibio said it was in discussions with a sleep clinic group to further validate its sleep staging technology in a prospective study, which would “open the opportunity for the company to commercialize this sleep staging algorithm as a stand-alone business opportunity in the area of home sleep monitoring and sleep clinics”.

The company said that sleep involved five stages, from stage one, two, three, four and the rapid eye movement stage and the diagnosis of sleep disorders required the determination of the sleep stages which was done using poly-somnography analysis, which included the collection of electro-encephalogram (EEG) data, breathing rates, eye movement and heart rate.

Medibio said that poly-somnography was invasive, expensive and not suited to the home setting, whereas ECG data could be measured using unobtrusive techniques promising the application for personal and continuous home sleep monitoring.

Medibio was unchanged at 31 cents.

TYRIAN DIAGNOSTICS, CONTANGO MICROCAP

Tyrian says that Contango Microcap will use it for a back-door listing of the management buy-out of CSM Holdings also known as Contango Asset Management.

Tyrian chairman Roger Amos told Biotech Daily that he would remain the chairman of the new entity, which would no longer have any direct involvement in biotechnology.

In a media release, Tyrian said it would consolidation its shares on a one-for-300 basis and raise $16.9 million through a prospectus share offer at 60 cents a share, or 0.2 cents a share on a pre-consolidation basis.

The company said that the offer was fully-underwritten by Taylor Collison and the proceeds would be used to fund the $13 million purchase price, subject to adjustments, and provide cash for working capital and to fund growth.

Tyrian said that Pacific Point Partners was an investment vehicle jointly controlled by James Packer and Robert Rankin and it had agreed to subscribe for 19.9 percent of Tyrian, post consolidation and completion of the offer.

The company said it would change its name to Contango Asset Management, subject to shareholder approval.

Tyrian said that the Melbourne-based Contango Asset Management had a Sydney office and a team of 12 investment professionals and used a combination of “top-down and bottom-up investment process”.

The company said that a notice of extraordinary general meeting would be mailed to shareholders in July 2016.

In 2012, Tyrian’s key staff resigned and the company said it had it had disposed of all fixed assets, ceased all further research and development work and vacated its facility at North Ryde (BD: Feb 24, 2012).

The company said at that time that the termination of agreements by Bayer Cropscience triggered the review and staff terminations (BD: Aug 24, 2011).

Tyrian was suspended at 0.1 cents.

GAMEDAY INTERNATIONAL

The Melbourne-based Gameday International Pty Ltd says it will backdoor into mining company Mount Magnet South to commercialize its sports mouth guards.

Mount Magnet South said it would conduct a one-for-20 consolidation, raise $3 million and be renamed Impression Healthcare.

The company said that it would issue 44,000,000 post-consolidation shares and 40,000,004 post-consolidation performance shares in consideration for the acquisition as well as seek approval for the issue of 9,687,500 post-consolidation shares and 1,171,879 post-consolidation note holder options exercisable at 12.8 cents each, as well as 37,500,000 shares to raise up to $3,000,000.

Mount Magnet South said that shareholders would vote to elect directors including Essendon Football Club coach John Worsfold, Alistair Blake, Kelvin Smith and Mathew Weston at a meeting to be held in Perth, Western Australia on July 27, 2016.

Mount Magnet South said that Gameday was established in September 2014 and was a manufacturer and distributor of home-impression custom-fit mouth guards and aimed "to disrupt the mouth guard market in Australia by enabling consumers to purchase custom made mouth guards in a more cost effective and convenient fashion than the traditional method of visiting a dental clinic".

The company said that Gameday allowed consumers to take an impression of their teeth at a time and place of their choosing using a Gameday impression kit, post the impression back to Gameday and receive a custom-fit mouth guard within 10 days.

Mount Magnet South said that Gameday had a single product range with product options including color design and/or the inclusion of their name and telephone number, costing about $80 each.

The company said that Gameday intended to investigate other products including teeth whitening products, dental splints, sleep apnoea appliances and boil-and-bite orthodontic mouth guards.