



# Biotech Daily

Wednesday September 16, 2015

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: IDT UP 18%; CLINUVEL DOWN 6%**
- \* **BIONOMICS BNC210 SAFE, NICOTINE RESPONSE**
- \* **ORTHOCELL ADDS DETAIL TO BONE CELL FACTORY STUDY**
- \* **BLUECHIIP EXPECTS \$50,000 MATCHED FEDERAL GRANT**
- \* **RHINOMED REQUESTS CAPITAL RAISING TRADING HALT**
- \* **BENITEC ADDS TEXAS METHODIST INSTITUTE TO TT-034 HEP C TRIAL**
- \* **ANATARA: 'DETACH REDUCES PIG SCOUR', DR HOLYOAKE ADVISOR**
- \* **MRCF-FUNDED AUSPHERIX EXPANDS DOMAINEX COLLABORATION**
- \* **GORDAGEN APPOINTS NATURAL ALTERNATIVES US MANUFACTURER**
- \* **VIRALYTICS 9m OPTIONS FOR M-D DR MCCOLL, CSO DR SHAFREN**

## MARKET REPORT

The Australian stock market rebounded 1.6 percent on Wednesday September 16, 2015 with the ASX200 up 89.5 points to 5,098.9 points. Twenty-one of the Biotech Daily Top 40 stocks were up, nine fell, three traded unchanged and seven were untraded.

IDT was the best on no news, up five cents or 17.9 percent to 33 cents with 486,025 shares traded, followed by Bionomics up 12.4 percent to 54.5 cents with 3.8 million shares traded.

Orthocell and Polynovo climbed more than nine percent; Avita, Living Cell and Medical Developments rose eight percent or more; Oncosil was up 7.7 percent; Ellex and Mesoblast were up more than four percent; Cellmid, Osprey, Prana and Sirtex were up more than three percent; Benitec, Optiscan and Universal Biosensors rose more than two percent; Actinogen, Admedus, CSL and Starpharma were up more than one percent; with Viralytics up 0.85 percent.

Yesterday's best, Clinuvel, led the falls, down 19 cents or 6.35 percent to \$2.80 with 5,178 shares traded. Anteo fell 4.8 percent; Tissue Therapies was down 3.8 percent; Impedimed, Nanosonics and Pharmaxis shed more than two percent; Atcor, Biotron and Prima were down more than one percent; with Cochlear and Resmed down by less than one percent.

## **BIONOMICS**

Bionomics says its phase Ib, multiple ascending dose, placebo-controlled trial of BNC210 for anxiety and depression has met its primary and secondary endpoints.

Bionomics said that BNC210 was an oral, negative-allosteric modulator of the alpha-7 nicotinic acetylcholine receptor and the trial showed it was safe and well-tolerated at all dose levels, a maximum tolerated dose was not reached and no subjects discontinued due to treatment-emergent adverse events.

The company said that consistent with its mechanism of action at the alpha-7 receptor, BNC210 significantly reduced the effect of nicotine measured by electroencephalogram. In February, Bionomics said the trial in more than 50 healthy volunteers was being conducted by the Rennes, France-based Biotrial International to investigate the safety, tolerability, pharmacokinetics and pharmaco-dynamics of BNC210 (BD: Feb 2, 2015). Biotrial research and development senior director Dr Philippe Danjou said that BNC210 had shown "an encouraging safety and tolerability profile and the demonstration that BNC210 modulates nicotine-dependent changes as measured by [electro-encephalogram] provides evidence of target engagement".

Dr Danjou said the data supported the continued development of BNC210.

Bionomics said that 54 healthy volunteers were enrolled and dosed for eight consecutive days, with 42 subjects receiving BNC210 in a range from 300mg to 2,000mg per day and 12 received a placebo.

The company said that in addition to safety evaluations, all study subjects underwent cognitive assessments, with subjective feelings also assessed.

Bionomics said that BNC210 administration did not result in adverse changes in cognition and there were no adverse changes in subjects' ratings of subjective feelings around alertness, contentedness or calmness and BNC210 administration did not result in feelings associated with drugs of abuse.

The company said that an additional pharmaco-dynamic test, the nicotine shift assay, was performed in subjects receiving either the highest dose of BNC210 or placebo and the subjects, all non-smokers, were administered nicotine by nasal spray with responses measured by EEG.

Bionomics said that of the 30 subjects administered with nicotine prior to administration of either BNC210 or placebo, 13 responded to nicotine in a dose dependent manner and the nicotine responders were selected for analysis.

The company said that when the study was unblinded, 12 of the nicotine responders received BNC210 while one nicotine responder received placebo.

Bionomics said that 11 BNC210-treated subjects showed evidence of reduction in nicotine-induced EEG measures relative to baseline while one BNC210-treated subject and the placebo-treated subject showed no changes in nicotine-induced EEG measures. The company said BNC210 significantly reduced EEG changes induced by half milligram incremental doses of nicotine from 0.5mg to 2mg ( $p < 0.02$  to  $p < 0.0009$ ).

Bionomics chief executive officer Dr Deborah Rathjen said that BNC210 "may offer differentiation from currently approved drugs for the treatment of anxiety and depression". "We look forward to progressing our current phase II trial in patients with generalized anxiety disorder and to considering other potential indications for BNC210 within the spectrum of anxiety disorders and depression," Dr Rathjen said. "Anxiety and depression have overlapping symptoms and an estimated 40 percent of patients with depression also have anxiety."

Bionomics said that its phase II trial on BNC210 for patients with generalized anxiety disorder was expected to report data by October, 2016 (BD: Apr 20, 2015).

Bionomics climbed six cents or 12.4 percent to 54.5 cents with 3.8 million shares traded.

## ORTHOCELL

Orthocell has clarified details of a study of the potential of its 'cell factory' derived bioactive molecules with an antibiotic containing bone substitute (BD: Sep15, 2015).

Orthocell said that the in-vitro combination study presented at the European Bone and Joint Infection Society in Estoril, Portugal September 10-12, 2015, did not relate to its "primary product focuses, which are the development of a stem cell treatment for the regeneration of human tendon tissue and the development of collagen based scaffolds for the reconstruction and regeneration of soft tissue injuries within the body".

The company said that the study was for a separate technology relating to the harvesting of tissue specific growth factors to aid in tissue healing and repair.

Yesterday, Orthocell reported that its cell factory-derived bioactive molecules from bone might enhance regeneration of slow healing bone defects common in chronic osteomyelitis and the new study "supported the role of growth factors and extracellular matrix proteins which were derived by the researchers from bone cells cultivated in a cell factory, to be combined with scaffolds, to regenerate serious bone defects".

Orthocell said that the study validated the concept using bone specific growth factors to aid in the regeneration of serious bone defects.

The company said the purpose of the study, co-authored by Orthocell chief scientific officer Prof Ming Hao Zheng, was to examine whether growth factors that might leak from a bone cavity could synergistically enhance the osteo-inductivity of a bone void filler as measured in a skeletal muscle cell line and an abstract was available at:

<http://prgmobileapps.com/AppUpdates/ors2015/Abstracts/abs1992.html>.

Orthocell climbed 5.5 cents or 9.5 percent to 63.5 cents with one million shares traded.

## BLEUECHIIP

Bluechiip says it has been hopes to receive Federal Government Entrepreneurs' Program Research Connections grant of up to \$50,000 for advice and facilitation services.

Bluechiip said that following participation in the facilitated service and working with a Research Connections facilitator it might "have access to financial assistance in the form of a matched funding grant worth up to \$50,000" for its bio-sample tracking system.

Bluechiip chief executive officer Andrew McLellan told Biotech Daily that under the program the total funds of up to \$100,000 would be paid to the partner research company. In a media release Mr McLellan said that the "funding, and more importantly access to researcher community, significantly enhances our ability to meet our strategic vision".

"The new technologies developed will expand Bluechiip's market attractiveness through high value Bluechiip [intellectual property] and products," Mr McLellan said.

The company said that Research Connections would be used to enhance its products through collaboration with the local research sector to respond to the specific feedback received during product trials.

Bluechiip said that the technologies would be initially applicable to bio-sample transport and storage with broader opportunities.

Bluechiip fell 0.2 cents or five percent to 3.8 cents.

## RHINOMED

Rhinomed has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on September 18, 2015 or on an earlier announcement.

Rhinomed last traded at 3.5 cents.

## BENITEC BIOPHARMA

Benitec says that the Dallas, Texas-based Methodist Health System Clinical Research Institute is the fourth site to join its phase I/Ila trial of TT-034 for hepatitis C.

In June, Benitec said it had dosed its sixth patient in the trial and “the first potentially therapeutic dose cohort” (BD: Mar 22, 2013; Apr 29, Jun 25, 2015).

Today, Benitec said the Institute had begun pre-screening patients and the site was led by principal investigator gastroenterologist and hepatologist Dr Parvez Mantry.

Benitec chief executive officer Dr French said that recruitment and dosing was “proceeding well”.

Benitec was up one cent or 2.1 percent to 49 cents.

## ANATARA LIFESCIENCES

Anatara says Detach reduces the number of pigs with diarrhoea by 41 percent and the severity by 45 percent and it has appointed Dr Trish Holyoake as clinical trial advisor.

Anatara chief executive Dr Paul Schober said that the bromelain, pineapple stem-based Detach results “reinforce our earlier successful field trial results”.

“Anatara is now focusing on completing a third and final field trial to support an application to register Detach with the Australian Pesticides and Veterinary Medicines Authority,” Dr Schober said.

The company said that the trial was conducted in 560 weaner piglets on a commercial pig farm in South Eastern Queensland that had a history of post-weaning disease caused by Escherichia coli.

Anatara said that despite the history of problems on the farm, there was a low incidence of scour and deaths during the trial period.

The company said that among the control group, two piglets died of unknown causes and two piglets were removed “due to ill-thrift”, with no deaths or removals due to ill-thrift in the Detach treated group.

On-line dictionaries define ill-thrift as the failure to grow, increase or maintain weight in the presence of adequate food supplies and in the absence of recognizable disease.

Anatara said the frequency of scour, or diarrhoea, in the control group was 152, while in the Detach group it was 89, a 41 percent reduction ( $p < 0.02$ ), with 21 occurrences of watery, or severe, scour in the control group, compared with seven in the Detach treated group, and Detach significantly reduced the severity of scour by 45 percent ( $p < 0.02$ ).

The company said there was a non-significant improvement in the final weight and average daily gain from weaning to 28 days post-weaning in the Detach-treated piglets.

Anatara chief scientific officer Dr Tracey Mynott said that Detach “showed a significant clinical benefit despite the lower than anticipated incidence of scour in this study”.

“Together with the first sucker trial, Detach has been shown to be effective in two different age groups of piglets, weaners and sucklers, in two major pig producing areas in different geographical areas, Northern Victoria and South East Queensland, and under two different clinical scenarios, extreme diarrhoea and death in Victoria, as well as mild conditions in Queensland,” Dr Mynott said.

Anatara said that subject to a successful third field trial and regulatory approval, Anatara was on track to launch Detach in Australia in 2016.

Anatara said it had appointed Dr Holyoake as a technical advisor on a part-time basis.

The company said that until recently, Dr Holyoake was the Victoria Pig Services Centre principal veterinary officer and she held a Bachelor of Veterinary Science and a Doctorate of Philosophy from the University of Melbourne.

Anatara was up two cents or 2.5 percent to 82 cents.

## AUSPHERIX

Auspherix says the collaboration with Domainex to develop drugs to tackle the growing threat of resistance to antibiotics has been expanded to 2017.

Auspherix said it was founded in 2013 based on discoveries at the University of Technology Sydney, raising \$2 million from the Brandon Capital-managed Medical Research Commercialisation Fund and more recently GBP6 million (\$A12.9 million) from the MRCF and the UK's Imperial Innovations Plc (BD: Jun 3, 2015).

The company said that progress had been made towards the invention of new compounds with activity against both gram-positive and gram-negative bacteria and the collaboration extension aimed to refine the current chemical series towards selection of novel pre-clinical candidates and to explore potential additional compound series.

Auspherix said it was building its UK-based microbiology and management teams at the Stevenage Bioscience Catalyst, intensifying discovery research on its initial bacterial disease focus and intending to explore further the potential in its antibiotic platform.

Auspherix co-founder and chief scientific officer Prof Ian Charles said the initial program were "on-track and making excellent progress".

"We believe the novel mechanism of action of our compound series discovered jointly with Domainex's scientists offers enormous potential for the development of a new arsenal of drugs that will be required to treat the growing numbers of bacterial infections," Prof Charles said.

Auspherix is a private company.

## GORDAGEN PHARMACEUTICALS

Gordagen says it has appointed the San Marcos, California-based Natural Alternatives International Inc to manufacture its food additive products for the US market.

Gordagen is developing vitamin E-derived tocotrienols for dietary supplements and prescription medicines.

Gordagen is a private company.

## VIRALYTICS

Viralytics says it will issue 5,000,000 options to managing director Dr Malcolm McColl, and 4,000,000 options to chief scientific officer Dr Darren Shafren.

Viralytics said that options would also be issued to senior management and performance rights to "a number of staff".

The company said that subject to shareholder approval, 5,000,000 options exercisable at 58.5 cents each within five years of issue, would be issued to Dr McColl, vesting in two tranches, with 4,000,000 options to be issued to chief scientific officer Dr Darren Shafren on the same terms.

Viralytics said that the options for Dr McColl and Dr Shafren would be subject to the achievement of milestones in 2016 and 2017 and recognized "their considerable past performance and the importance of retaining them and rewarding their work".

Viralytics was up half a cent or 0.85 percent to 59.5 cents.