



Biotech Daily

Tuesday May 29, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: GENETIC TECHNO UP 10%, NEUREN DOWN 7%**
- * **WRONG CONTROL KILLS NEUREN CANCER TRIAL; DR BAINS GOES**
- * **BIONICHE CLAIMS VACCINE FOR E COLI IN BEEF**
- * **CSIRO GRANTED US, EURO shRNAi GENE SILENCING PATENTS**
- * **NUSEP LODGES PATENT APPLICATIONS FOR WASTE BLOOD PROCESS**
- * **IMPEDIMED RETAIL RIGHTS OFFER RAISES \$844k; \$8.7m TOTAL**
- * **ACTINOGEN DIRECTOR DAVID ZOHAR BAILED FOR ALUMINEX IPO**

MARKET REPORT

The Australian stock market was up 1.14 percent on Tuesday May 29, 2012 with the S&P ASX 200 up 46.4 points to 4,114.4 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and eight were untraded.

Genetic Technologies was the best, up 1.5 cents or 10.3 percent to 16 cents with 1.8 million shares traded.

Anteo climbed 6.6 percent; Allied Health was up 4.35 percent; Prima and Sunshine Heart were both up 3.7 percent; Alchemia, Cochlear and Phylogica rose more than two percent; Optiscan and Viralytics were up more than one percent; with Acrux, Pharmaxis, Resmed and Sirtex up by less than one percent.

Neuren led the falls, having climbed as much as 0.5 cents or 20 percent to three cents before closing down 0.2 cents or 7.4 percent to 2.5 cents with 50.2 million shares traded.

Both Cellmid and Compumedics were down 6.25 percent; Antisense, Benitec, Bioniche and Biota fell five percent or more; Avita was down 4.4 percent; Tissue Therapies was down three percent; Phosphagenics shed 2.9 percent; Mesoblast and Reva were down more than one percent; with CSL, Heartware and Starpharma down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says a trial of the monoclonal antibody TFF1.4 will have to be repeated following the supply of an active antibody instead of a true control.

Neuren said the study was being conducted through its Perseis Therapeutics joint venture with the New Zealand Breast Cancer Research Trust which was developing monoclonal antibodies against two trefoil factors, TFF-1 and TFF-3.

Neuren said that TFF-1 and TFF-3 were proteins expressed by a wide range of cancers that increased the spread of the tumor, decreased its susceptibility to current therapy and were associated with more metastatic disease and poorer survival in patients.

Neuren said the first target was TFF-1 in breast cancer which was being targeted with human monoclonal antibodies produced from antibody fragments selected from a fragment library developed by the University of California San Francisco.

The company said that the fragments were selected by screening them for binding against the TFF protein then tested against a human breast cancer cell line in vitro and the first xenograft experiment had been completed.

Neuren said that of the two monoclonal antibodies tested, TFF1.4, resulted in a statistically significant reduction in tumor volume of about 35 percent, compared to a vehicle control as well as three-fold higher survival at the end of the experiment.

The company said that xenograft experiments typically included an antibody control, that is, an antibody raised against a target that is unrelated to the disease target, to differentiate between any possible non-specific antibody effect and the specific effect of the antibody being tested.

Neuren said that "a technical error on the part of a supplier resulted in our using an antibody directed against a known cancer target which meant that it was biologically active and not a true control".

The company said that TFF1.4 "outperformed that antibody but the study will need to be repeated to measure TFF1.4 effect against a true control".

"These results, however, support our belief that anti-TFF antibodies inhibit proliferation of human cancer and represent a promising therapeutic approach," Neuren said.

Neuren said that based on the xenograft study results it had decided to fund the next step in the program and had formed a relationship with the Maryland-based Noble Life Sciences to develop a stable cell line to produce TFF1.4 antibodies fully capable of going from laboratory to market.

Neuren said that Noble specialized in development of drugs and biologics for cancer, was founded by former senior staff from Human Genome Sciences and Medimmune and would repeat the xenograft study

Neuren said that Noble had capabilities from discovery through clinical trials and would help ensure that development of TFF1.4 was accelerated and that all facets of the program met industry standards.

Neuren said that former co-chief executive officer Dr Parmjot Bains has decided to leave the company.

Neuren said that with the prioritizing of the anti-TFF project as a core program, chief executive officer Larry Glass would assume direct oversight of Perseis, including the relationship with Noble.

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BIONICHE LIFE SCIENCES

Bioniche says that a Public Health Agency of Canada study backs its Econiche vaccine to prevent outbreaks of illness caused by *Escherichia coli* O157:H7 in Canadian beef. Bioniche said the study assessed the effects of interventions on the management of *Escherichia coli* O157:H7 in Canadian beef and supported pre-slaughter vaccines such as the Econiche cattle vaccine.

The company said the study entitled 'A risk assessment model for *Escherichia coli* O157:H7 in ground beef and beef cuts in Canada: Evaluating the effects of interventions' had been accepted for publication in the journal Food Control.

The article is at: <http://www.sciencedirect.com/science/article/pii/S0956713512001223>.

Bioniche said the authors evaluated the public health risks associated with consumption of ground beef and beef cuts contaminated with *Escherichia coli* O157:H7 in Canada and evaluated the relative effects of pre-slaughter and processing interventions on public health risks, comparing the baseline risks from consumption of beef products.

Bioniche said the research included findings from critical systematic review and meta-analysis of published literature and 20 different intervention scenarios were assessed.

The company said that pre-harvest interventions assessed included probiotics, a siderophore receptor and porin protein vaccine, and a type III protein vaccine.

Bioniche said Econiche was a type III protein vaccine.

The researchers concluded that the most effective strategy for *E coli* O157:H7 management included a pre-harvest intervention and several processing interventions: "Specifically, application of type III secreted protein vaccination along with a suite of processing interventions ... provided the greatest relative reduction in risks." Bioniche said.

Bioniche said it was trying to gain widespread uptake of cattle vaccination with Econiche and had since 2008 a full licence in Canada.

The company said that farmers who adopted the technology were small producers with a branded beef product concerned about the negative impact of an *E coli* outbreak on their brand, and farmers whose cattle had infected humans with *E coli* O157.

Bioniche said that outbreaks and recalls associated with *E coli* O157 infection and contamination occurred on a regular basis.

The company said it had been in dialogue with the US Department of Agriculture since 2008 and was eligible for a conditional licence once certain conditions were met.

Bioniche said that ruminants, primarily cattle, were the primary carriers of *E coli* O157, which could cause severe illness and could be fatal when ingested by humans from contaminated meat, vegetables, other food products, or water.

Human exposure and infection with *E coli* O157 could result in serious health consequences, including abdominal pain and severe diarrhoea and in severe cases, kidney damage could occur and progress to serious complications and even death.

Bioniche said that about 100,000 cases of human infection with the *E coli* O157 organism were reported each year in North America and two to seven percent of those people developed haemolytic uremic syndrome, a disease characterized by kidney failure, and five percent of those patients died.

The article said that the analysis "indicated that risks from consumption of ground beef were approximately two to three orders of magnitude greater than those for beef cuts, suggesting that risk management measures should focus on the former product to maximize benefits to public health ... [and] risks from consumption of non-intact beef cuts, that is, steaks or roasts that are tenderized, were an order of magnitude greater than those for intact beef cuts," the study found.

Bioniche fell two cents or five percent to 38 cents.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation has been granted patents in the US and Europe for short hairpin RNAi gene silencing technology.

A CSIRO media release said that short hairpin RNA interference (shRNAi) gene silencing technology was used as a research tool to test the function of genes and was being developed for a range of targeted therapies in humans.

The CSIRO said that potential human therapeutic applications using shRNAi included protection against viruses such as HIV or hepatitis and animal applications included the selection of production traits in livestock and the treatment of, and protection against, diseases such as influenza in chickens.

The Organisation said the US patent entitled 'Methods and means for obtaining modified phenotypes' and the European patent entitled 'Means and methods for modifying gene expression using unpolyadenylated RNA' substantially strengthened its already extensive RNAi portfolio of more than 60 granted patents, stemming from the pioneering work of CSIRO Plant Industry scientists who were the first to develop hairpin RNAi in 1997.

Benitec licences CSIRO intellectual property around RNAi for human therapeutics.

CSIRO said that hairpin RNAi technology was first used in plants and had revolutionized the search for genes responsible for valuable traits and had been developed for use in animals, particularly in mammals where shorter RNAi molecules were commonly used.

ACTINOGEN

Actinogen director David Alan Zohar has been charged with providing false or misleading information and bailed to appear in the Perth Magistrates Court on August 15, 2012

The Australian Securities and Investments Commission said that Mr Zohar, of Inglewood, Western Australia was charged with three counts of providing false or misleading information to the Australian Securities Exchange, following an ASIC investigation.

ASIC said it was alleged that as a director of Aluminex Resources Mr Zohar "allowed the provision of false or misleading information to the ASX in connection with Aluminex's ASX listing in September 2008".

ASIC said in a media release that Aluminex was suspended by the ASX on October 13, 2008 and was required to make full refunds to all subscribers of the shares under its prospectus.

ASIC said that each charge carried a maximum penalty of two years imprisonment.

ASIC said that Mr Zohar appeared in the Perth Magistrates Court on May 25, 2012 and did not formally enter a plea and that bail was granted and the matter adjourned for a committal mention at Perth Magistrates Court on August 15, 2012.

ASIC said the Commonwealth Director of Public Prosecutions was prosecuting the matter.

ASIC said that Aluminex Resources was exploring for bauxite and other metals east of Perth and the charges came from an investigation into the initial public offering in which Aluminex sought to raise up to \$10 million with a minimum subscription of \$2.5 million.

ASIC said that Aluminex was admitted to the official list of the ASX on September 24, and suspended on October 13, 2008 as a result of its inability to satisfy the ASX that it had met the requirements for listing.

ASIC said that on November 5, 2008, Aluminex said it might not have received cleared funds in excess of the minimum amount of \$2.5 million specified in its prospectus.

ASIC said that as a result of the regulator's intervention, Aluminex made refunds to all the persons who had subscribed for shares under the prospectus, which was finalized in November 2008 and was removed from the Official List on July 31, 2009.

Actinogen was untraded at 2.6 cents.

NUSEP

Nusep says it has lodged two provisional patents with IP Australia (formerly the Australian Patent Office) covering the disposable manufacturing process of plasma products.

Nusep said the patent applications covered the core of the Prime Biologics business model including the use of non-regulated plasma from countries, such as India, fractionating this plasma using a disposable production process to manufacture therapeutic plasma products.

The company said the patent applications, along with other patents and non-disclosed technology formed the basis of the intellectual property that it had incorporated into its wholly owned Singapore subsidiary Prime Biologics (BD: Apr 26, 2012).

Nusep was up 0.1 cents or 2.9 percent to 3.5 cents.

IMPEDIMED

Impedimed has raised \$844,234 from retail investors through applications for 2,412,096 shares at 35 cents a shares in its non-renounceable one-for-four rights issue.

Earlier this month Impedimed raised \$7.8 million from institutional investors through the rights issue and had hoped to raise up to \$5.9 million from retail investors.

Impedimed said it had raised a total of \$8.7 million.

Impedimed was unchanged at 32 cents.