

# Biotech Daily

Thursday May 21, 2009

Daily news on ASX-listed biotechnology companies

- \* ASX DOWN, BIOTECH UP: AVEXA UP 18%, CYTOPIA DOWN 8%
- \* BIONOMICS' BNC210 FOR ANXIETY APPROVED FOR HUMAN TRIALS
- \* TYRIAN WHEAT TEST READY FOR NORTH AMERICA
- \* BIOSIGNAL FOUNDER, CEO PROF PETER STEINBERG RESIGNS
- \* HEALTHLINX AIMS FOR 97% RESULT IN MAJOR OVARIAN CANCER TRIAL
- \* BIO-BRIEFING: WHAT THE BRUCE GRAY CASE MEANS FOR RESEARCH
- \* SIRTEX FREE OF UWA v DR BRUCE GRAY CASE
- \* CHEMGENEX PRESENTS THREE PAPERS AT EUROPEAN MEETING
- \* VICTORIA, CALIFORNIA IN \$29m STEM CELL COLLABORATIONS

# **MARKET REPORT**

The Australian stock market fell 0.28 percent on Thursday May 21, 2009 with the S&P ASX 200 down 10.7 points to 3,813.9 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and seven were untraded.

Avexa was best, up two cents or 18.2 percent to 13 cents with 5.3 million shares traded, followed by Biota up 17.5 percent to \$1.34 with 2.5 million shares traded and Viralytics up 12.9 percent to 3.5 cents.

Bionomics climbed 6.4 percent; Acrux, Benitec, Chemgenex, Nanosonics and Progen were up more than five percent; Living Cell was up 4.8 percent; Antisense, Cochlear, Genera and Pharmaxis climbed more than three percent; Clinuvel and Mesoblast rose more than two percent; with CSL and Heartware up by less than one percent.

Cytopia led the falls, down 0.7 cents or 7.61 percent to 8.5 cents with 10,000 shares traded, followed by Peplin down 7.3 percent to 69.5 cents.

Phosphagenics and Phylogica lost more than six percent; Genetic Technologies and Novogen fell five percent or more; Circadian was down 4.35 percent; Alchemia lost 3.8 percent; with Arana, Resmed and Sirtex down by less than one percent.

# **BIONOMICS**

Bionomics says anti-anxiety compound BNC210 has passed ethics review and is approved for human clinical trials.

Bionomics said the first clinical trial of BNC210 would be at the Royal Adelaide Hospital with the University of Adelaide's professor of clinical pharmacology Prof Paul Rolan as principal investigator.

The company said the primary goals of the trial would be to evaluate the safety and tolerability of BNC210 and its pharmacokinetics.

Preclinical data showed that BNC210 was fast-acting and effective with a single daily oral dose in a range of small animals and was able to reduce anxiety without the common side effects of drowsiness, impairment of memory and motor function, Bionomics said. Bionomics chief executive officer Dr Deborah Rathjen said the approval marked "a major

Bionomics chief executive officer Dr Deborah Rathjen said the approval marked "a major achievement for Bionomics, which in the space of two years, has progressed two drug candidates to clinical trial".

"From a commercial stand-point, I believe BNC210 is a key asset in to our pipeline," Dr Rathjen said.

"The market for anxiety drugs is enormous and BNC210 appears to have key features of competitive advantage when compared with existing treatments," Dr Rathjen said.

The company said anxiety was "a common debilitating condition that affects 19 million patients in the US alone and has an estimated market value \$US5-\$12 billion worldwide". Bionomics said many of the largest blockbuster drugs were for treating anxiety including Valium, Prozac, Paxil, Buspar and Zoloft.

Prof Rolan said there had been "no fundamentally new and effective treatments for anxiety for decades".

"Of the treatments we do have, many patients are burdened by side-effects," Prof Rolan said.

"BNC210 appears to be entirely novel in its action and remarkably free of the sedation associated with other treatments for anxiety," he said.

Bionomics was up 1.5 cents or 6.38 percent to 25 cents.

#### **TYRIAN**

Tyrian says it has completed the manufacture of an initial order of commercial Readrite alpha amylase kits for Bayer Cropscience for Canada and the US.

Tyrian said the Readrite test detected alpha-amylase in wheat and performed well in an independent evaluation which confirmed it as a reliable measure of wheat quality.

The company said the test was formerly known as Wheatrite and was being marketed in Canada as the Readrite alpha amylase test for use with Tyrian's Reader.

Tyrian's chief executive officer Dr Jenny Harry told Biotech Daily the company's primary focus was respiratory and infections disease tests with the lead test being developed for active tuberculosis.

Dr Harry said Tyrian would receive revenue for the manufactured wheat quality test as well as licencing fees and royalties.

Tyrian was unchanged at 3.4 cents.

# **BIOSIGNAL**

Biosignal's founder and chief executive officer Prof Peter Steinberg has resigned following the takeover of his board by Empire Investments (BD: Apr 28, May 6 and 7, 2009).

Prof Steinberg is also the inventor of Biosignal's technology based on the eastern Australian seaweed Delisea pulchra which produces natural furanones that disable bacteria's ability to colonize.

The technology has been tested in a range of anti-microbial applications from medical instruments to contact lenses as well as oil and gas pipes.

Biosignal said it was "in receipt of certain commercial proposals that it is reviewing which are likely to necessitate a change in management".

"Accordingly Prof Steinberg has offered his resignation to the company as CEO and director," Biosignal said.

On April 28, 2009, Biosignal announced it had raised \$120,000 through the placement of 12,000,000 shares (9.2%) to the previously unknown Western Australia-based Empire Investments, with a requirement that Empire approve three directors.

On May 6, 2009 the three Empire directors resigned over "philosophical differences". On May 7, 2009 Biosignal said they would be replaced by Manraj Khosa, Timothy

Morrison and Prof Michael Henderson.

Mr Khosa said at that time that due to confidentiality provisions he could not reveal the identity of the principals or directors of Empire Investments.

Today Biotech Daily asked Mr Khosa whether the company would continue with its antimicrobial technology or look for a different technology to commercialize.

Mr Khosa said all options were being discussed and the board was still considering them. He declined to answer whether the board would be able to find a scientist to develop the anti-microbial technology.

Biosignal climbed 0.2 cents or eight percent to 2.7 cents with 1,080,000 shares traded.

#### **HEALTHLINX**

Healthlinx says it has secured collaborators in Australia, Asia and the United Kingdom for a second larger study for its Ovplex early stage ovarian cancer diagnostic.

Healthlinx said the main aim of the trial was to demonstrate ovarian cancer accuracy for Ovplex to an unprecedented 97 percent or greater diagnostic efficiency.

The company said the study of up to 1155 patient samples would also establish the value of the two novel biomarkers HTX005 and HTX010 in improving test performance. Healthlinx said the collaborators would contribute plasma samples, knowledge and expertise for the biomarker trial.

The company said preliminary Ovplex data suggested that diagnostic efficiency could be increased to greater than 97 percent.

The study will screen the samples using the original five biomarker panel as well as the two new novel biomarkers HTX005 and HTX010, allowing the company to clinically validate the new biomarkers and generate the best possible combination of biomarkers. Healthlinx said the Ovplex panel would be based on a simple blood test.

The company said it had executed a distribution agreement with Intus Health Care to distribute Ovplex in the UK and Ireland.

Healthlinx managing director Nick Gatsios said that having secured "almost 50 percent of the samples needed for the study means that we are on track to commence the trial during the fourth guarter this calendar year".

Healthlinx climbed half a cent or 11.1 percent to five cents.

# **BIO-MELBOURNE NETWORK**

The Bio-Melbourne Network says the imminent verdict in the University of Western Australia versus Dr Bruce Gray case will have significant implications for research. The case initially involved Sirtex Medical of which Dr Gray was the founder and former chairman and remains a major shareholder.

The issues involving Sirtex have been settled by the courts (BD: May 15, 2009) but the Bio-Melbourne Network says the case has implications for research institutes, universities and commercial entities where academic and non-commercial research is performed. The Network said the University of Western Australia case tested the presumption that the employer owns the intellectual property rights to the works done by the employee. At the June 10, 2009 Bio-Briefing, Sirtex's legal counsel Edward Heerey will provide background to the case and explore the issues surrounding the "date of invention". Mr Heerey will discuss the grounds of the appeal being lodged and the implications for universities and research institutes and answer the question many university and research institutes would like to know: 'What is the University of Western Australia's ability to claim ownership of inventions created by its research staff?'

Mr Heerey will discuss the likely outcomes of one of the most controversial Federal Court cases in Australia.

The Bio-Briefing will be held at Pricewaterhouse Coopers, Freshwater Place, Level 19, 2 Southbank Blvd, Southbank.

Registration is from 3:45pm, the Bio-Briefing starts at 4pm and will be followed at 5:30pm by networking and drinks.

For more information go to <a href="www.biomelbourne.org">www.biomelbourne.org</a>, email <a href="mailto:npitcher@biomelbourne.org">npitcher@biomelbourne.org</a> or call Nicole Pitcher on +613 9650 8800.

#### SIRTEX

In the edition of Friday May 15, 2009 Biotech Daily reported that Sirtex could not be contacted to answer two remaining questions regarding the long running court case. Sirtex chairman Richard Hill called Biotech Daily shortly after publication on the Friday to confirm that the May 15 decision was the end of Sirtex's involvement in the case. Mr Hill said that the payment of Dr Gray's costs in that particular matter was "miniscule" by comparison to the costs to be paid to Sirtex for the more substantial matter, which is expected to be heard in November 2009 in the Federal Court in Western Australia. Sirtex fell one cent or 0.33 percent to \$3.04.

#### CHEMGENEX

Chemgenex says new data from two clinical studies and a pre-clinical study of omacetaxine will be presented at the European Hematology Association in Berlin, in June. Chemgenex said the latest clinical data from the pivotal study on the use of omacetaxine in chronic myeloid leukemia patients with the T315I mutation will be given by Dr Mauricette Michalletof the Hôpital Edouard Herriot, Lyon, France.

Interim data from the company's complementary phase II study investigating the potential use of omacetaxine in patients with resistance to multiple tyrosine kinase inhibitors will be presented by the Roswell Park Cancer Institute's Dr Meir Wetzler.

The University of Glasgow's Dr Elaine Allen will present the results of a collaborative project investigating the ability of omacetaxine to kill human malignant chronic myeloid leukemia stem cells which are insensitive to the tyrosine kinase inhibitors.

Chemgenex climbed 2.5 cents or 5.26 percent to 50 cents.

# **VICTORIAN GOVERNMENT**

Victorian and Californian will collaborate in a \$US22 million (\$A28.7 million) stem cell program of four research projects.

In a media release, Innovation Minister Gavin Jennings said the funding grants were "the first step in a three-year collaboration" established last year between the Victorian Government and the California Institute for Regenerative Medicine (CIRM), that will establish strategic projects on stem cell research aimed at accelerating treatments of disease.

Other joint projects focus on moving basic research toward therapies by addressing safety, quality and technical hurdles in the safe use of stem cells for human therapies. "This collaboration highlights that Victoria and California are world leaders in biotechnology and stem cell research, and the Brumby Government is taking action with this project to improve the quality of life of the millions of people around the world suffering from Alzheimer's disease, Parkinson's disease and diabetes," Mr Jennings said. Mr Jennings said the projects were the first to emerge since he and Premier John Brumby signed the agreement last year with CIRM president Alan Trounson to establish a pan-Pacific 'stem cell airbridge'.

The Victorian Government will fund the Victorian teams while CIRM will fund the Californian teams. There are four joint projects so far being funded by the alliance. The media release said Victoria was home to specialist stem cell centres such as the Australian Stem Cell Centre, Monash Immunology and Stem Cell Laboratory and the Australian Regenerative Medicine Institute.

The four projects are 'Methods for detection and elimination of residual human embryonic stem cells in a differentiated cell product' which is led by Prof Andrew Elefanty and Prof Ed Stanley for Monash University and Novocell Inc; 'Neural Stem Cells as a Developmental Candidate to Treat Alzheimer's Disease' led by Prof Richard Boyd for the Australian Stem Cell Centre, Monash University and the University of California Irvine; 'Ensuring the safety of cell therapy: a quality control pipeline for cell purification and validation' led by Dr Andrew Laslett for the Australian Stem Cell Centre and Scripps Research Institute; and 'Developmental Candidates for Cell-Based Therapies for Parkinson's Disease led by Dr Clare Parish and Prof Colin Pouton for the Florey Neuroscience Institutes, Monash University and Burnham Institute for Medical Research.