



# Biotech Daily

Tuesday November 15, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: NEUREN UP 12%; PSIVIDA DOWN 14%**
- \* **MESOBLAST: CARDIAC STEM CELLS SHOW SAFETY, EFFICACY**
- \* **WEHI'S PROF STRASSER WINS \$50k VICTORIA, \$100k SMORGON PRIZES**
- \* **BIONOMICS DETAILS BNC201 PANIC ATTACK TRIAL DATA**
- \* **CALZADA REMUNERATION REPORT 1<sup>st</sup> STRIKE**
- \* **CRYOSITE PLEADS SCHULTZ TO ASX 38% QUERY**
- \* **CONSEGNA APPOINTS BRENDAN FLEITER DIRECTOR**

## MARKET REPORT

The Australian stock market fell 0.44 percent on Tuesday November 15, 2011 with the S&P ASX 200 down 19.0 points to 4,285.6 points.

Eight of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and five were untraded.

Neuren was the best, up 0.3 cents or 12.0 percent to 2.8 cents with 19.1 million shares traded, followed by Alchemia up 7.1 percent to 30 cents with one million shares traded.

Patrys climbed 4.1 percent; Circadian was up 3.1 percent; Sirtex rose 2.15 percent; with Anteo, Cochlear, CSL and Tissue Therapies up more than one percent.

Psivida led the falls for the second day in a row, down 30 cents or 14.3 percent to \$1.80 with 14,400 shares traded, followed by Uscom down 10.3 percent to 13 cents with 7,050 shares traded.

Genetic Technologies and Prana lost more than six percent; Impedimed and Mesoblast were down more than five percent; Avita and Cathrx fell more than four percent; Biota, Living Cell, Nanosonics and Viralytics were down more than three percent; Prima and Sunshine Heart shed more than two percent; with Acrux, QRX and Pharmaxis down one percent or more.

## MESOBLAST

Mesoblast says one of 45 cardiac disease patients treated with its Revascor adult stem cells died, compared with three of the 15 untreated controls.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that the low dose treatment with his company's mesenchymal precursor cells (MPCs) increased left ventricular ejection fraction, while the higher doses didn't, but more important than the volume of blood ejected by the heart, was the incidence of hospitalization or death, along with measures such as the six-minute walk test and the time to major adverse cardiac event. Prof Itescu said that none of 15 patients in the high dose 150 million Revascor cell group died or was hospitalized at 18 months of follow-up.

Prof Itescu did not want to guess at why the low dose of mesenchymal precursor cells (MPCs) increased ejection fraction, but the higher doses did not.

Prof Itescu said he was aware of the Lancet article published yesterday in which cardiac stem cells increased ejection fraction but did not report on other measures.

The article was entitled 'Cardiac stem cells in patients with ischaemic cardiomyopathy (SCIPIO): initial results of a randomised phase I trial' and an abstract is available at:

[www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2961590-0/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2961590-0/abstract).

"The FDA and other regulators in Europe and Australia are only interested in cardiac mortality and hospitalization," Prof Itescu said. "Ejection fraction is not an acceptable end-point, either alone or in combination."

He said the difference in doses showed that ejection fraction was "decoupled" from cardiac remodeling and that the highest dose could be showing a reduction in scarring and fibrosis.

"All three doses prevent death," Prof Itescu said. "The highest dose prevented hospitalization and death in both ischemic and non-ischemic patients."

Last year, Mesoblast used ejection fraction as a measure of myocardial function in its sheep trial, saying that ejection fraction in treated subjects was a mean of 12 points higher than in controls (54.4 +/- 1.1% compared to 42.5 +/- 3.6%;  $p < 0.001$ ) and that every tested dose significantly reduced left ventricular dilation, with mean end systolic volumes in treated subjects 66 +/- 1.0 mL compared with 98.6 +/- 5.1 mL in saline-treated controls ( $p < 0.001$ ) (BD: Nov 16, 2010).

Today, Mesoblast said that treatment with its adult stem cells was well-tolerated, with 13 percent of patients developing transient or persistent anti-donor antibodies which were without clinical consequence.

The company said that treatment significantly delayed the time to a first major adverse cardiac event, a composite of cardiac death, heart attack or revascularization procedures ( $p = 0.036$ ) and reduced the overall risk by 78 percent ( $p = 0.011$ ).

Mesoblast said that over a mean follow-up of 18 months, none of 15 patients who received the highest dose of 150 million cells had been hospitalized for heart failure or had died, compared with three of 15 controls and six of 30 patients who received low dose 25 million cells or mid-dose 75 million cells and were hospitalized or had died.

The company said that the clinical improvement associated with the high dose was accompanied by evidence of cardiac remodeling such as the reduction in left ventricular end systolic volumes compared with controls at six months, ( $p = 0.015$ ) and improved functional capacity measured by a gain of 52.6 meters over a six minutes' walk compared with controls at 12 months ( $p = 0.06$ ).

Mesoblast said that after 12 months, 40 percent of all treated patients had reverted to class I NYHA heart failure status compared with 14 percent of all controls, and this effect remained when patients were matched for the presence of class II status at baseline.

Mesoblast fell 45 cents or 5.5 percent to \$7.75 with 1.3 million shares traded.

## VICTORIA GOVERNMENT PRIZE, FELLOWSHIPS, SMORGON AWARD

The Walter and Eliza Hall Institute for Medical Research's Prof Andreas Strasser won this year's \$50,000 Victoria Prize and the \$100,000 Anne and Eric Smorgon Award.

Announcing the awards at the Victoria Parliament, the Minister for Innovation Louise Asher said that the awards for science and technology were important to the Baillieu Government and acknowledged the previous Labor Government's contribution to research and innovation.

"We want Victoria at the forefront of innovation," Ms Asher said.

Ms Asher said Prof Strasser won the Victoria Prize for his work in understanding how programmed cell death or apoptosis could cause autoimmune diseases or cancer and prevent tumor cells from responding to anti-cancer therapies.

The institution that supports the Victoria Prize winner is awarded the \$100,000 Smorgon family prize.

Ms Asher said that it was the 10<sup>th</sup> year that the Smorgon family had supported the prizes and they had contributed \$1 million in total in this particular award, as well as the family's significant contribution in other areas of health and medical research.

Ms Asher said the Victoria Prize saluted the most outstanding achievements, recognizing and rewarding the hard work of those who had contributed to the community.

In accepting his award, Prof Strasser said it was very important to encourage the young scientists who received the \$18,000 Victoria Fellowships and gave credit to his own students and post-doctoral students for their contributions, along with Prof Suzanne Cory who recruited him to the Walter and Eliza Hall Institute when he had "a poor ceevee".

WEHI director Prof Doug Hilton accepted the \$100,000 Smorgon Award and told biotech daily that the funds would go directly to Prof Strasser's research team.

Ms Asher also announced the six winners of \$18,000 Victoria Fellowships to assist researchers travel to undertake short-term international study missions.

Ms Asher said that Australian French Association for Science and Technology would also provide a further \$5,000 each to winners who chose to study in France.

University of Melbourne Bio21 Institute synthetic chemistry research fellow Dr Brett Paterson was awarded a Victoria Fellowship for diagnostic molecular agents for use in detecting early stage cancer.

A Victoria Government media release said Dr Paterson designed a new chemical reaction for molecules to help target tumors to provide accurate diagnosis of cancer.

The media release said Dr Paterson had a patent to protect his work and had established his own company, Clarity Pharmaceuticals.

The media release said the Fellowship will allow Dr Paterson to travel to King's College, London, to use the copper-64 radioactive isotope, a technology not available in Australia.

University of Melbourne Faculty of Microbiology and Immunology Ph D student Jaclyn Pearson was awarded a Fellowship for her work on the interaction between Escherichia coli and human cells and will study at the Institut Pasteur in Paris.

The Royal Children's Hospital's cardiology fellow Dr Darren Hutchinson won his Fellowship to undertake specialist training to establish a Victorian Foetal Cardiology Unit.

Three non-medical awards went to Liang Chen to develop technology to improve internet transmissions, Dr Mandy de Souza for her work on lighter stronger vehicle surfaces and Dr Jean-Pierre Veder for his research into environmentally friendlier solvents.

Ms Pearson and Dr Veder also won the \$5,000 Australian French Association for Science and Technology prizes.

A spokesperson for Ms Asher told Biotech Daily, that pending State Budget circumstance, the Government intended doubling the number of Victoria Prizes and Fellowships, next year.

## BIONOMICS

Bionomics has presented its phase Ib panic attack trial results demonstrating efficacy with reduced sedation and intellectual impairment (BD: Mar 30, 2011).

The poster was presented by Bionomics BNC210 project leader Dr Sue O'Connor at the Society For Neuroscience conference, in Washington DC and said that BNC210 produced a statistically significant reduction of both the total number and total intensity of the panic-like symptoms induced by a CCK-4 injection in healthy male subjects, observed at 10 minutes post CCK-4 injection.

The poster said that BNC210 produced a positive trend on the emotional stability of subjects with a CCK-4 induced panic attack and the reduction of panic symptoms provided evidence for the anxiolytic activity of BNC210 in humans in a challenge setting.

The poster said the finding was supported by the electroencephalogram data presented at a previous conference, showing that BNC210 produced an increase in fast beta activity, associated with the anxiolytic activity of benzodiazepines.

The poster said that adrenocorticotrophic hormone (ACTH) and cortisol levels were increased in response to the CCK-4 injection: a single oral dose of BNC210 significantly reduced the ACTH levels ( $p = 0.04$ ) at five minutes post CCK-4 injection.

BNC210 treated subjects had a 94 percent probability of having less than four symptoms on the panic symptom scale compared to placebo treated subjects.

The poster said a single oral dose of BNC210 was safe and well tolerated with no serious adverse events and that a single dose of BNC210 significantly reduced ( $p = 0.048$ ) the total number of symptoms on the panic symptom scale 10 minutes after CCK-4 injection.

Subjects on BNC210 experienced 37.7 percent fewer symptoms than controls and a single dose of BNC210 significantly reduced ( $p = 0.041$ ) the intensity of symptoms on the panic scale at 10 minutes post CCK-4 injection.

Bionomics chief executive officer Dr Deborah Rathjen said the Society For Neuroscience meeting was seen by industry as the premium opportunity to highlight advances in central nervous system drug development and to learn about the competitive landscape.

"For Bionomics, presenting at this highly attended scientific meeting guarantees that our clinical data will get maximum exposure in the international neuroscience community and raise the global profile of BNC210 as an innovative next generation treatment for anxiety and depression," Dr Rathjen said.

Bionomics was unchanged at 39.5 cents.

## CALZADA

More than 25 percent of votes cast at Calzada's annual general meeting opposed the remuneration report, with chairman David Franklyn elected overwhelmingly.

The remuneration report was approved with 94,981,582 proxy votes (74.54%) in favor and 32,441,152 proxy votes (25.46%) against.

According to the Australian Securities and Investments Commission, changes to the Corporations Act (Section 250U) provide for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.

The adoption of the employee option plan was passed by a similar margin.

According to the ASX, Fleming SG Capital Special Opportunities holds 29,158,903 shares.

Mr Franklyn was elected with more than 123.5 million votes in favor and 987,020 votes against.

Calzada was up 0.1 cents or 1.8 percent to 5.6 cents.

## CRYOSITE

Cryosite has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 10.5 cents on November 7, 2011 to 14.5 cents on November 14, 2011, a 38.1 percent increase and noted an increase in trading volume.

Antisense said that it expected clinical trial results for its growth hormone receptor targeting drug ATL1103 by the end of this year and reaffirmed the timeline at its annual general meeting on November 8, 2011.

The company said that as "general market information: it occasionally received "confidential, non-binding expressions of interest from third parties in relation to such matters as proposals for joint activities and proposals for the acquisition/merger of parts of the company's business" and had received such an offer in recent months but the expression of interest was not an offer capable of acceptance.

"Further communication from the third party in question after the initial approach, has led the company to believe that the third party is no longer pursuing that proposal [and] the company is not in negotiations in relation to any expression of interest," Cryosite said.

Cryosite said that at its annual general meeting on November 7, 2011 the chairman the company had strong operational performance, profitability and cash flow for the past 12 months and a positive operational outlook for the next 12 months.

The company said its shares were "relatively illiquid, with the result that any trading in the company's shares can have a material impact on share price".

Cryosite was untraded at 14.5 cents.

## CONSEGNA GROUP

Consegna (formerly Helicon) says it has appointed Brendan Fleiter as a non-executive director.

Consegna said Mr Fleiter was a commercial lawyer, before spending 13 years with the Crazy John's group as a non-executive director and chief executive officer.

The company said Mr Fleiter was a non-executive director of People Telecom for seven years before its merger with M2 Telecom and was a non-executive director of Australia Post and a director of several not-for-profit organizations.

Consegna fell 0.3 cents or 8.8 percent to 3.1 cents with 3.2 million shares traded.