Biotech Daily

Thursday October 20, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTEO UP 10%; LIVING CELL DOWN 27%**

*** NEUREN PRICE JUMPS 81% ON BELL POTTER NOTE, ROADSHOW**

*** PRANA, MHRI'S DR PAUL ADLARD WINS $763k NHMRC GRANT**

*** VIRALYTICS BEGINS PHASE II CAVATAK MELANOMA RECRUITMENT**

*** US GPA ADDS 175k LIVES TO IMPEDIMED LYMPHOEDEMA TEST**

*** ELLEX PREVIEWS INTEGRE PRO LASER AT US CONFERENCE**

*** ALLIED'S ROBERT TOWNER GOES NON-EXECUTIVE; CO SEC CHANGE**

MARKET REPORT

The Australian stock market fell 1.63 percent on Thursday October 20, 2011 with the S&P ASX 200 down 68.8 points to 4,144.9 points.

Ten of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and 10 were untraded. All three Big Caps fell.

Anteo was the best, up 0.6 cents or 10 percent to 6.6 cents with 6.7 million shares traded, followed by Prana up 9.7 percent to 17 cents with 28,531 shares traded.

Patrys was up 4.8 percent; Clinuvel, Genera and Genetic Technologies were up more than three percent; Mesoblast and Reva were up more than one percent; with Acrux and Starpharma up by less that one percent.

Living Cell led the falls, retreating 2.8 cents or 26.7 percent to 7.7 cents with 10 million shares traded, following yesterday's 144 percent rise, followed by Antisense down 11.1 percent to 0.8 cents with 1.6 million shares traded.

Sunshine Heart lost 6.7 percent; Cellmid fell 5.3 percent; Alchemia and Bionomics fell more than four percent; Psivida was down 3.6 percent; Allied, QRX and Resmed shed more than two percent; with Biota, Cathrx, Cochlear, CSL, Nanosonics and Tissue Therapies down more than one percent.

NEUREN PHARMACEUTICALS

Neuren has told the ASX that a Bell Potter analysis may have pushed its share price 81.25 percent to 2.9 cents on strong volumes.

The ASX queried the price rise from 1.6 cents on October 18 to a high today of 2.9 cents.

The company said the analysis by Stuart Roberts had been posted on its website, concluding with a target share price of 12 cents.

Mr Roberts and Neuren chief executive officer Larry Glass met investors and analysts in Melbourne today and told Biotech Daily the company's phase II trials had no financial risk.

Mr Roberts said Mr Glass was well-connected to the US Army's biomedical research "three-star general" officials and the US Army spent $2.8 billion a year on research.

Mr Roberts said Neuren had $23 million in US Army and Australian National Health and Medical Research Council non-dilutive funding for its two phase II trials.

Mr Glass said the company was conducting a phase II trial of Motiva (nefiracetam) for post-stroke depression and apathy, which could also have application for Parkinson's and Alzheimer's disease.

Mr Glass said that Motiva had "an extraordinary safety profile" having been tested in 2,700 people, but an earlier trial by another company had design faults that meant there was a question of whether it was treating apathy and depression or apathy alone.

Mr Glass said that Neuren's 122-patient phase II trial of Motiva for stroke with apathy but not depression would inform a phase III trial design.

Mr Glass said that intra-venous NNZ-2566 was in a 260-patient dose-ranging phase II trial for moderate to severe traumatic brain injury, with more than 50 patients enrolled.

"All the direct costs, manufacturing and clinical trials are covered by the Army," Mr Glass said, adding that enrolment should be completed by the end of 2012, with results in 2013.

But Mr Glass said that the US Food and Drug Administration had agreed that if the trial was successful, the company would be required to conduct a single pivotal phase III trial with 500 to 600 patients, rather than the usual two trials and if all went smoothly, the pivotal trial would be completed in 2015 or 2016.

Mr Glass said the company was formulating an oral version of NNZ-2566 for mild traumatic brain injury.

He said that NNZ-2566 was a synthetic analog of Insulin-like growth factor 1 (IGF-1) a naturally occurring neuro-peptide.

Mr Glass said that after a brain injury there was an up-regulation of inflammatory cytokines which led to a cascade of inflammation and neuronal cell death.

He said NNZ-2566 inhibited the up-regulation of the cytokines and was hoped to reduce the non-convulsive, or silent, seizures that caused further brain damage.

Mr Glass said the trial had three primary endpoints including the Glasgow Coma Scale, the Portland Adaptability Index and biological outcomes including seizures as measured by electro-encephalogram, blood biomarkers of cell death and intra-cranial pressure.

He said the FDA had approved the trial meeting any one of the three efficacy endpoints.

Mr Glass said there was a $4 billion US market for traumatic brain injury with no approved drugs and only one competitor in development, the hormone progesterone.

Mr Glass said that eight of the 20 US key opinion leaders were investigators in the trial and the other 12 were on Neuren's advisory board.

He said NZ-2566 had "many other potential indications including penetrating brain injury, stroke, cardiac arrest, perinatal asphyxia and silent seizures in other injuries.

Mr Glass said pre-clinical work had shown NNZ-2566 potential for use in a form of autism known as Rett's syndrome, with non-growing cell dendrites resuming growth and long-term potentiation, with the possibility of bringing children "back to normal".

Neuren was up 0.1 cents or 4.35 percent at 2.4 cents with 61.1 million shares traded.

PRANA BIOTECHNOLOGY, VICTORIA MENTAL HEALTH RESEARCH INSTITUTE

Prana says that researcher Dr Paul Adlard has won a $762,975 National Health and Medical Research Council grant to study PBT2 and other compounds in age-related cognitive impairment.

Prana said that Dr Adlard was the head of the synaptic neurobiology laboratory at Victoria's Mental Health Research Institute as well as one of its research scientists.

The company said the grant application was for 'The role of metals in healthy brain ageing: identification of novel compounds to prevent age-related cognitive decline'.

Prana said PBT2 was its lead drug for Alzheimer's and Huntington's diseases.

Prana executive chairman Geoffrey Kempler said the "highly competitive grant from the Australian Federal Government will fund the study of compounds including PBT2, researching effects on brain anatomy and biochemistry and also cognition and behavior".

"Earlier this year, Dr Adlard published a landmark paper in the science journal PLoS One, describing how PBT2 restores healthy function to neurons damaged in an animal model of Alzheimer's disease," Mr Kempler said.

Prana said it had previously reported that in older normal mice, which were not genetically bred to develop Alzheimer's, the cognitive decline normally associated with the ageing process was significantly improved or reversed by PBT2.

The company said that the grant would allow Dr Adlard to extend the evidence for the role of the biological metals targeted by PBT2, in both Alzheimer's disease as well as normal age-related cognitive loss.

Prana said that the normal ageing process and age-related disorders such as Alzheimer's disease were characterized by a decline in cognitive processes, with memory impairment one of the most debilitating features of both normal and pathological ageing.

The company said there were no effective long-term treatments, or even a defined understanding of how these deficits occur.

Dr Adlard said the grant would support testing the hypotheses of "the cause and potential treatments of memory impairments, specifically linking synaptic zinc dyshomeostasis as a causative factor, and indeed as a therapeutic target, of this dysfunction".

"PBT2, already shown to bring cognitive benefit to Alzheimer's disease patients may also improve the cognitive decline associated with normal ageing," Dr Adlard said.

Prana was up 1.5 cents or 9.7 percent to 17 cents.

VIRALYTICS

Viralytics says patient recruitment has begun in its US phase II trial of Cavatak for melanoma, following approval from the first of a series of institutional review boards.

Viralytics said it expected approval from three more US sites in the next four to six weeks.

The company said the Mount Sinai Comprehensive Cancer Center in Miami, Florida was the first approval and its principal investigator Dr Jose Lutzky said he expected the trial to accrue well, given therapeutic progress in the melanoma field with immunotherapeutic approaches, including encouraging reports with the use of oncolytic viral vaccines.

Viralytics said the phase II trial will have up to 63 patients with 54 evaluable and was a single arm intra-tumoral trial, injecting Cavatak into multiple tumous on up to 10 separate occasions over an 18 week period.

The company said the primary endpoint would measure immune-related progression-free survival at six months.

Viralytics chief executive officer Bryan Dulhunty said patient recruitment was expected to proceed quickly.

Viralytics was unchanged at 46 cents.

IMPEDIMED

Impedimed says the US Group & Pension Administrators will cover more than 175,000 lives for its bio-impedance spectroscopy to diagnose post-breast cancer lymphoedema.
Impedimed said that Group & Pension Administrators covering the use of its L-Dex diagnostic for lymphoedema was important because it was one of the largest independently owned third-party benefit administrators in the south-western US and an active promoter of women's health.
The company said Group & Pension Administrators “strongly endorses the pre-emptive model of care for lymphoedema in breast cancer patients’.
Group & Pension Administrators chief operations officer Kathy Enochs said that as a prevention champion, her company “strongly promotes health plan coverage for oncologists to clinically assess the early stages of lymphoedema because it is the right thing to do for the patient and plan”.
Impedimed chief executive officer Greg Brown said that “growing numbers of companies see becoming self-insured as a means of controlling cost while improving quality of care for employees”.
“We are excited by the announcement which demonstrates [Group & Pension Administrators] focus on women’s health issues and because of their prominence in the south-west,” Mr Brown said.
“They recognized the value of the pre-emptive model of care and the use of L-Dex as an aid in the clinical assessment of unilateral lymphoedema of the arm in women,” Mr Brown said.
Impedimed was unchanged at 50 cents.

ELLEX MEDICAL LASERS

Ellex says it will preview its laser platform Integre Pro for the treatment of retinal disease.
Ellex said the Integre Pro was the first photocoagulation laser to offer customized configuration of multiple laser wavelengths in a fully integrated, laser slit lamp microscope design and would be launched at the meeting of the American Academy of Ophthalmology October 22 to 25, 2011.
The company said that unlike competitive systems, which required an external slit lamp microscope in order for the ophthalmologist to perform treatment, the Integre Pro had integrated the laser with the slit lamp microscope.
Ellex said the design would enable ophthalmologists to perform both diagnosis and treatment and was the next evolution of its existing Integre laser platform.
Ellex chief executive officer Tom Spurling said the Integre Pro was an “intelligent platform [that] enables physicians to take advantage of the full spectrum of retinal laser treatments in a fully integrated design”.
“Our unique, patented design allows physicians to both diagnose and treat retinal disease using the one system, saving the physician time and money and giving us a considerable competitive advantage,” Mr Spurling said.
Ellex said that Increases in life expectancy, lifestyle changes and diet continue to contribute to an increased incidence of retinal disease, offering growth potential for the Integre Pro.
“Historically, our focus has been on the photo-disruptor laser market for the treatment of secondary cataract,” Mr Spurling said.
Ellex said the system would be commercially available from 2012.
Ellex was unchanged at 12 cents.

ALLIED HEALTHCARE GROUP

Allied Health says Biomd co-founder Robert Towner has become a non-executive director and chief financial officer Stephen Mann as company secretary.

Allied said that current company secretary Darren Bromley would remain as a consultant.

The company said Mr Towner was a founding director of Biomd and integral in the merger of the two companies (BD: Jun 14, 2011).

Allied said Mr Mann joined Allied Medical in January 2011 having worked in both the public and private corporate sector, specializing in management reporting, system improvement, financial management and mergers and acquisitions.

The company said Mr Mann held a Bachelor of Business degree.

Allied fell 0.1 cents or 2.8 percent to 3.5 cents.