Biotech Daily

Monday November 21, 2011

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: CELLMID UP 12.5%; GENERA DOWN 16%**

*** NEUREN DOSES 2nd PHASE II BRAIN INJURY COHORT, 3rd GROUP READY**

*** EUROPE APPROVES STARPHARMA PHASE III VAGINOSIS TRIAL**

*** ETHICS APPROVAL FOR PHOSPHAGENICS PAIN TRIAL**

*** GENETIC TECHNOLOGIES' EASY AGM**

*** VIRALYTICS APPOINTS DR LEONARD POST DIRECTOR**

*** CBIO LOSES DIRECTORS DR PETER CORR, DR GORAN ANDO**

*** PROF GRAEME CLARK WINS $50,000 AIPS, CSL FLOREY GONG**

MARKET REPORT

The Australian stock market fell 0.34 percent on Monday November 21, 2011 with the S&P ASX 200 down 14.0 points to 4,163.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, eight fell, 11 traded unchanged and eight were untraded.

Cellmid was the best, up 0.2 cents or 12.5 percent to 1.8 cents, with 920,000 shares traded followed by Neuren up 7.4 percent to 2.9 cents with 29.5 million shares traded.

Sunshine Heart climbed 5.3 percent; Bionomics was up 4.55 percent; Allied Health was up three percent; Biota rose 2.1 percent; with Cochlear, Phylogica, Starpharma and Tissue Therapies up more than one percent.

Genera led the falls, down 2.5 cents or 16.1 percent to 13 cents with 2,590 shares traded.

Alchemia and Psivida lost more than six percent; Phosphagenics, QRX and Viralytics shed more than two percent; with Anteo and Clinuvel down more than one percent.

NEUREN PHARMACEUTICALS

Neuren has enrolled the second cohort of 30 patients in its phase II trial of NNZ-2566 for traumatic brain injury and has begun enrolment of the 200-patient third cohort.

Neuren said there were no serious adverse events in the second cohort reported as drug-related.

The company said that as part of the third cohort, implementation of the protocol approved under exception from informed consent (EFIC) provisions was in progress allowing enrolment of patients for whom it was not possible to obtain informed consent from a legally authorized representative.

Neuren said the provision was restricted to life-threatening conditions, where immediate treatment was required and there was no alternative treatment available.

Neuren said the phase II trial would evaluating the safety and efficacy of intravenous administration of NNZ-2566 in patients with moderate to severe traumatic brain injury.

The company said the drug was administered within eight hours of injury (within six hours under EFIC) via a 10 minute bolus followed by 72 hours of continuous infusion.

Neuren said that all patients received the same bolus dose (20mg/kg/hr) or placebo, with the first 30 patients (cohort 1) receiving a low-dose continuous infusion (1mg/kg/hr) or placebo, the next 30 patients (cohort 2) receiving an intermediate dose infusion (3mg/kg/hr) or placebo and the third cohort of 200 patients receiving the highest infusion dose (6mg/kg/hr) or placebo.

The company said that all doses were intended to produce blood levels of the drug in patients that were comparable to the range in which efficacy was confirmed in animal models of brain injury.

Neuren said it was also developing an oral form of NNZ-2566 to treat patients who had a concussion, a milder type of head injury than the traumatic brain injury being targeted with the intravenous form of the drug.

The company said that concussion was more than four times as common as moderate or severe traumatic brain injury, frequently occurring in people participating in sports and as a result of falls and motor vehicle accidents.

Neuren said that additional toxicology and pharmacokinetic studies in animals had been completed and showed the oral form to be safe with minimal side effects.

The company said that a phase I safety and pharmacokinetic study in healthy volunteers was planned to be undertaken in Australia in early 2012, with a phase II trial in concussion patients expected in mid-2012.

Neuren said that in addition to concussion, it had begun development of the oral form of NNZ-2566 for Rett syndrome, a severe, physically disabling disease part of the autism spectrum disorders, with no approved drug treatment.

The company said it expected file an investigational new drug application for the Rett syndrome study in the second half of 2012 and to initiate the trial in late 2012.

Neuren chief executive officer Larry Glass said the company was pleased that NNZ-2566 appeared to be well-tolerated in traumatic brain injury patients.

“We are also gratified that the changes instituted in the study have improved the pace of enrolment and remain confident that enrolment will continue to accelerate in cohort three with the inclusion of female as well as younger and older patients and as EFIC is implemented,” Mr Glass said.

“Progress with the oral formulation has been excellent and we are excited about the new clinical programs that we believe will significantly increase the value of the NNZ-2566 franchise,” Mr Glass said

Neuren was up 0.2 cents or 7.4 percent to 2.9 cents with 29.5 million shares traded.

STARPHARMA

Starpharma says the European Medicines Agency has agreed its phase III clinical trial program for Vivagel for bacterial vaginosis treatment.
Starpharma said the European scientific advice was in addition to the agreement reached with the US Food and Drug Administration.
The company said that positive phase III results in Europe and the US would support approval of the product.
Starpharma said it planned to begin its phase III bacterial vaginosis treatment program early in 2012 with completion expected before the end of the year.
The company said that the two phase III studies would be conducted in parallel and the design was “very similar” to its phase II trial of Vivagelfor the treatment of bacterial vaginosis, with the same primary endpoint of clinical cure, as assessed by resolution of symptoms and other standard clinical criteria and the comparator would be a placebo gel.
Starpharma chief executive officer Dr Jackie Fairley said the company looked forward to beginning the program “early in the New Year and, following our recent financing, we plan to add some additional trial sites to further expedite its completion”.
The company said that following the completion of phase III trials it planned to partner the product.
Starpharma was up 1.5 cents or 1.35 percent to $1.13.

PHOSPHAGENICS

Phosphagenics says it has ethics approval to begin a phase I clinical trial of its tocopheryl phosphate mixture oxycodone patch for chronic pain.
Phosphagenics said the 65-patient trial would begin at the CMAX facilities at the Royal Adelaide Hospital by the end of November 2011.
The company said that the pharmacokinetic study would examine the safety and tolerability of the patch, which had been optimized in collaboration with the 3M company.
Phosphagenics said the trial was designed to examine the oxycodone delivery profile of the patch, with the first stage administering a single dose patch and the second stage examining repeat dosing.
The company said that the study would be used to design the phase III trial scheduled to begin by October 2012.
Phosphagenics said the new patch was superior to the original in-house developed prototype and in a series of in-vitro studies the newly developed patch delivered greater amounts of oxycodone over a longer period of time resulting in a reduction of the size of the patch and a commercial finish.
Phosphagenics chief executive officer Dr Esra Ogru said the trials were designed to capture the pivotal data that would form the basis of the investigational new drug application regulatory submission to the US Food and Drug Administration and ensure the phase III trials proceeded as seamlessly as possible.
“We expect this trial will confirm the superior efficacy of the optimized commercial product and demonstrate a sustained drug delivery appropriate for the treatment of chronic pain,” Dr Ogru said.
Phosphagenics fell half a cent or 2.9 percent to 16.5 cents.

GENETIC TECHNOLOGIES

The main business of Genetic Technologies annual general meeting was over in about 20 minutes with all resolutions passed overwhelmingly.

The meeting was a contrast to the 2008 meeting when founder, former chief executive officer and largest shareholder Dr Mervyn Jacobson ousted five directors and took control of the company (BD: Nov 19, 2008)/

Today, Genetic Technologies chief executive officer Dr Paul MacLeman told the meeting that the company had achieved all of its objectives from the 2010 annual meeting, including positing its maiden profit and ending the year “cash-flow positive”, along with earning $14 million from licencing, in large part attributed to Dr Jacobson, along with the roll-out of the Brevagen test in the US and reviewing prospective merger and acquisition targets.

Dr MacLeman said that of about 20 projects had been considered with detailed due diligence conducted on two projects, currently in negitations.

Dr MacLeman said that the US Food and Drug Administration effectively required diagnostic tests for all new cancer drugs and that was a benefit for his company.

He said Genetic Technologies was in discussions with an unnamed “big pharma” for a potential partnership.

Dr MacLeman said that without a diagnostic, the company was having difficulty selling its $50,000 a year drug.

Dr MacLeman said the Brevagen test was on sale in the US at $US945 per test with a potential market of 1.2 million patients a year.

Dr MacLeman said the company had a “soft launch” in Australia, where the test was available for $300.

He said the company recently had its forensic testing contract renewed by the New South Wales Police Force and had less formal arrangements with the Queensland State Government, Victoria Police and Western Australia Police.

Genetic Technologies was unchanged at 12.5 cents.

VIRALYTICS

Viralytics says that Dr Leonard Post has been appointed as a non-executive director.

Viralytics said Dr Post had extensive experience in oncolytic viruses and virotherapy having been a past director of and consultant to Biovex, which was recently acquired by Amgen Inc.

The company said that Dr Post was senior vice president of research and development at Onyx Pharmaceuticals, one of the first companies involved in the development of targeted oncolytic viruses.

Viralytics said Dr Post had about 20 years experience with large pharmaceutical companies and a strong commercial background.

The company said Dr Post was the chief scientific officer of Biomarin Pharmaceuticals.

Viralytics said Dr Post had a PhD in Virology from the University of Chicago and was adjunct professor of microbiology and immunology at the University of Michigan, with more than 60 scientific publications and was an inventor on numerous patents.

Viralytics fell one cent or 2.1 percent to 47 cents.

CBIO

CBio says two more directors have resigned with the departure of Dr Peter Corr and Dr Goran Ando.

In September, a shareholder action group requisitioned a meeting to force the resignation of founder and chairman Stephen Jones along with directors Prof John Funder and James Greig (BD: Sep 5, 7, 2011).

All three eventually resigned ahead of the requisitioned meeting, with a board statement that all the company's existing directors would resign if any of three action group proposed directors were elected.

Despite the election, the existing directors did not resign at that time, saying that they had reviewed their decision.

Today, CBio said that Dr Peter B Corr was the co-founder and managing general partner of Celtic Therapeutics Management and a former Pfizer senior vice president for science and technology.

The company said Dr Ando was the chairman of Symphogen AS, Copenhagen and vice chairman of Novo Nordisk AS Copenhagen.

CBio fell half a cent or 2.7 percent to 18 cents.

AUSTRALIAN INSTITUTE OF POLICY AND SCIENCE, CSL

Bionic ear pioneer Prof Graeme Clark is expected to be awarded the $50,000 CSL Florey Medal at Parliament House in Canberra tonight.

A media release from the Australian Institute of Policy and Science and CSL said the award would be given at the Association of Australian Medical Research Institute's annual dinner.

The Australian Institute of Policy and Science said it was "an independent and non-partisan not-for-profit organization first founded in 1932" and the Howard Florey medal had been presented every two years since 1998 to honor Prof Florey's work on the development penicillin.

The media release said that "over the past 30 years hundreds of thousands of people have had their lives transformed by Graeme Clark's invention".

The media release said that Prof Clark joined previous winners including Nobel Laureates Prof Barry Marshall and Dr Robin Warren, Prof Colin Masters for his pivotal work on Alzheimer's disease, Prof Peter Coleman, who unveiled the structure of the influenza virus, leading to Biota's anti-influenza drug Relenza and Prof Ian Frazer, for the development of the Gardasil vaccine against cervical cancer.

CSL chief scientist Dr Andrew Cuthbertson said the Prof Clark was "a fitting winner".

"Prof Clark had a big idea and took it through a tortuous scientific and regulatory path to create a device that has transformed the lives of people around the world," Dr Cuthbertson said.

"His ideas have seeded many other initiatives in bionics," Dr Cuthbertson said.

The media release said that the Florey Medal was awarded biennially to an Australian biomedical researcher for significant achievements in biomedical science and/or human health advancement.