Biotech Daily

Thursday December 10, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VIRALYTICS UP 8%; LBT DOWN 24%**

*** CSL'S R&D PIPELINE FOCUS ON HEART, DENTAL DISEASE**

*** LIVING CELL HAILS NHMRC ADVICE TO LIFT XENOTRANSPLANT BAN**

*** BIOTA CEO PETER COOK DEFENDS TAMIFLU FROM BMJ ARTICLE**

*** EASTLAND REQUISITIONS BERLIN PHARMA GOVERNANCE EGM**

*** UNIVERSAL BIOSENSORS BANKS $17.5m; SHIPS FIRST GLUCOSE STRIPS**

*** J&J'S TIBOTEC EXTENDS AVEXA HIV OPTION 4 MONTHS**

*** VIRAX APPLIES FOR US PATENT**

*** KARMELSONIX SIGNS AUSTRALIAN WHEEZOMETER DISTRIBUTOR**

*** SOLAGRAN PLEADS SCHULTZ TO ASX 26% PRICE FALL QUERY**

MARKET REPORT

The Australian stock market fell 0.7 percent on Thursday December 10, 2009 with the S&P ASX 200 down 31.2 points to 4606.7 points.

Six of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and eight were untraded.

Viralytics was best, up 0.3 cents or 7.7 percent to 4.2 cents with 902,416 shares traded, followed by Prana up one cent or 6.25 percent to 17 cents with 122,500 shares traded.

Starpharma climbed 3.6 percent; Alchemia and Universal Biosensors rose more than two percent; with Nanosonics up 1.7 percent and Cochlear up 0.26 percent.

LBT (formerly Labtech) led the falls, down 2.5 cents or 23.8 percent to eight cents with 211,162 shares traded, followed by Sunshine Heart down 12.5 percent to 3.5 cents.

Compumedics and Psivida lost more than seven percent; Living Cell fell 5.6 percent; Acrux, Biota and Sirtex were down more than four percent; Avexa, Cellmid and Clinvel were down more than three percent; Mesoblast and Phosphagenics shed more than two percent; with Bionomics, Chemgenex, CSL, Optiscan and Pharmaxis down more than one percent.

CSL

CSL says it spent $311 million on research and development in 2008-'09 and employed 750 scientists, mostly in Australia.

CSL's chief scientific officer Dr Andrew Cuthbertson said in the Sydney research and development presentation and teleconference that the company conducted a large range of activities but focused the discussion on two projects involving a natural human protein to reduce cholesterol in cardiac arrest patients and a recombinant vaccine to protect against Porphyromonas gingivalis with causes widespread dental illness.

CSL's Dr Sam Wright said the company produced CSL111, a reconstituted high density lipoprotein recovered from blood that normally went into the production waste stream.

Dr Wright said there were 450,000 deaths a year in the US from coronary heart disease generally caused by the build up of cholesterol into arthrosclerosis.

Dr Wright said the low density lipoprotein (LDL) carried cholesterol to the heart and high density lipoprotein (HDL) removed the cholesterol.

He said animal studies showed that infusions of high density lipoproteins reduced the artery plaque build up by 60 percent compared to placebo in five to seven days.

Dr Wright said about 20 clinical trials had taken place involving "hundreds" of patients.

He said the hope was that infusions of the recovered high density lipoprotein could prevent repeat cardiac arrests in patients admitted to hospital after an initial event.

Dr Wright said the company had developed CSL112 and hoped to begin trials in 2010.

CSL chief scientific officer Dr Andrew Cuthbertson said the cost of the trials would begin in the millions of dollars for phase I, "tens of millions of dollars" for phase II and "could be $100 million" for the phase III trial.

The chief executive officer of the Cooperative Research Centre for Oral Health at the University of Melbourne's Dental School Prof Eric Reynolds said Porphyromonas gingivalis was a leading cause of periodontal disease with one in four adults having the disease, recognized by bleeding gums when brushing teeth and eating.

Prof Reynolds said periodontitis led to teeth falling out and was associated with other diseases including cardiovascular disease, oropharyngeal cancer and pancreatic cancer.

He said large scale prospective studies had shown that even with management 13.5 percent of patients experienced disease progression.

Prof Reynolds said Porphyromonas gingivalis was known as the "microbial vampire" because the bacteria had developed to live in blood.

In animal models where the Porphyromonas gingivalis had been genetically removed there was no disease.

Prof Reynolds said animals could be immunized with Porphyromonas gingivalis, but with CSL and Sanofi-Pasteur, a recombinant protein vaccine was being developed.

He said domestic animals also had periodontitis.

Prof Reynolds said the standard treatment was to remove plaque which grew back in about one month. If the vaccine could be developed for humans an antibiotic would be given after plaque cleaning to keep the Porphyromonas gingivalis at bay while the vaccine was being absorbed.

Prof Reynolds said human clinical trials were "a long way to go" and estimated the earliest would be 2012 to 2013.

He said a vaccine could also be developed as a prophylactic as the disease generally began in late adolescence. He said there was no strong link to diet, but the addition of fluoride to water meant people were keeping their teeth longer and the increase in periodontitis was probably due to the increase in people keeping their teeth as Porphyromonas gingivalis resided in tooth roots.

CSL fell 35 cents or 1.15 percent to $30.15 with three million shares traded.

NHMRC, LIVING CELL TECHNOLOGIES

The National Health and Medical Research Council says that, pending stringent regulation, the 2004 Australian moratorium xenotransplantation should be lifted.

Living Cell, is conducting trials in Russia and New Zealand on the safety and efficacy of using encapsulated pig islets of Langerhans to produce insulin for type 1 diabetic patients and welcomed the NHMRC decision.

The NHMRC said animal to human transplantation required "stringent regulatory and surveillance frameworks" to be put in place.

NHMRC chairman Prof Michael Good said the Council noted the developments in science and technology since 2004, in particular evidence relating to the risks of transmission of animal viruses.

The NHMRC media release specifically noted that "international experience has largely been in the area of using insulin-producing cells from a pig pancreas to treat a person with type 1 diabetes".

"After careful consideration, the Council is of the view that, although there is a wide range of community views on the topic, xenotransplanation research was acceptable in Australia when there are robust regulations in place," Prof Good said.

"Council has taken into account a range of issues including the risk of viral transmission and the evidence available on the safety of the therapy for individuals and the wider community," he said.

NHMRC chief executive officer Prof Warwick Anderson said the process for testing new procedures through clinical trials could take many years and involved several phases.

"Trials would be able to proceed once ethical approval has been given and the Therapeutic Goods Administration has implemented a robust framework to regulate clinical trials involving xenotransplantation," Prof Anderson said.

"Further the NHMRC, using the advice of its Australian Health Ethics Committee and Animal Welfare Committee, would now develop guidance for researchers and ethics committees involved in animal-to-human studies," Prof Anderson said.

"The NHMRC will also work with the Australian Government's Department of Health and Ageing to determine appropriate surveillance and monitoring frameworks to support clinical trials going forward," he said.

Living Cell said it hoped to expand its clinical trial program into Australia, following the National Health and Medical Research Council decision to lift the five-year moratorium on xenotransplantation in Australia.

Living Cell's chief executive officer Dr Paul Tan said the company "very much" welcomed the decision by the NHMRC and was pleased the original concerns had been satisfied.

"This is in keeping with recent scientific data and the increasing acceptance of current international guidelines for the safe use of animal tissue to treat human disease," Dr Tan said.

"This decision opens up significant opportunities not only for [Living Cell], but for the wider medical science community and people with life threatening diseases," Dr Tan said.

Living Cell said that in November 2008, the World Health Organisation released the Changsha Communiqué which addressed the potential and importance of xenotransplantation and outlined the parameters for xenotransplantation research and trials. The company said it was compliant with all the guidelines and has a designated pathogen-free pig herd.

Living Cell said it was "the only company in the world conducting xenotransplantation phase II trials in diabetes and has previously reported early encouraging results from Diabecell trials in New Zealand and Russia".

Living Cell fell 1.5 cents or 5.6 percent to 25.5 cents.

BIOTA, BRITISH MEDICAL JOURNAL, ROCHE

An article on Riche's neuraminidase inhibitor Tamiflu (oseltamivir) in the British Medical Journal has sparked widespread media coverage discussing efficacy and cost.

An introduction by the Journal, the analysis and Roche's responses are all available at http://www.bmj.com.

Biota produced its alternative neuraminidase inhibitor Relenza which is licenced to Glaxosmithkline and chief executive officer Peter Cook rejected the criticism in the British Medical Journal.

"This class of criticism can't be defended because the company is seen to have a vested interest and the regulators role isn't to indulge in public debate," Me Cook said.

"But people shouldn't lose sight of the fact that the regulators have a rigorous and extended process of full scientific evaluation," Mr Cook said.

In a lead article entitled 'Pandemic influenza - The truth about Tamiflu?' the British Medical Journal (Dec 8, 2009; BMJ 2009;339:b5106) said the Cochrane group's update of a 2005 review of oseltamivir in pandemic influenza concluded: "Neuraminidase inhibitors have modest effectiveness against the symptoms of influenza in otherwise healthy adults. The drugs are effective post-exposure against laboratory confirmed influenza, but this is a small component of influenza-like illness, so for this outcome neuraminidase inhibitors are not effective. Neuraminidase inhibitors might be regarded as optional for reducing the symptoms of seasonal influenza. Paucity of good data has undermined previous findings for oseltamivir's prevention of complications from influenza. Independent randomized trials to resolve these uncertainties are needed."

The research article entitled 'Neuraminidase inhibitors for preventing and treating influenza in healthy adults: systematic review and meta-analysis' said its objectives were "to update a 2005 Cochrane review that assessed the effects of neuraminidase inhibitors in preventing or ameliorating the symptoms … transmission …and complications from influenza in healthy adults, and to estimate the frequency of adverse effects".

The article concluded that neuraminidase inhibitors "have modest effectiveness against the symptoms of influenza in otherwise healthy adults".

"The drugs are effective post-exposure against laboratory confirmed influenza, but this is a small component of influenza-like illness, so for this outcome neuraminidase inhibitors are not effective. Neuraminidase inhibitors might be regarded as optional for reducing the symptoms of seasonal influenza. Paucity of good data has undermined previous findings for oseltamivir's prevention of complications from influenza. Independent randomized trials to resolve these uncertainties are needed," the article said.

Roche was quoted saying it had "robust procedures for both producing and sharing study reports. As well as providing reports to such regulatory bodies, Roche has … willingly shared data and reports with numerous other eligible individuals and groups, including the Cochrane review group … the authors of the cited publications and numerous others, and other research groups".

"In the case of oseltamivir, as well as the documented benefits to those in high risk groups, these aims are particularly relevant in the context of the current H1N1 (2009) flu pandemic and the ongoing threat from highly pathogenic H5N1 (avian) flu infection," Roche was reported saying. "The role of oseltamivir in mitigating the serious threats from such flu infections has been recognized in the recommendations from the World Health Organization. We continue to pursue these aims through active and thoroughly conducted research programs, constantly updated ethical practice, and extensive collaborations with international experts in their fields. Why Dr Jefferson and the BMJ chose to pursue their scientific enquiries through commercial television remains to be clarified."

Biota fell 12 cents or 4.1 percent to $2.79 with 1.4 million shares traded.

EASTLAND MEDICAL SYSTEMS

Eastland has requisitioned an extraordinary general meeting of HC Berlin Pharma following a review of its activities.

Eastland said it was the largest shareholder in Berlin Pharma a company listed on the Frankfurt Stock Exchange and the review was commissioned by Eastland's German lawyers Lovells LLP.

The company said Berlin Pharma was established principally as a contract manufacturer of pharmaceutical products in Potsdam and holds the rights to contract manufacture Eastland's Artimist anti-malarial treatment primarily for children with complicated malaria.

Eastland said that among the items on the agenda was the dismissal of the supervisory board members Rudolf Schötteldreier and Douglas A Sims; tabling of annual financial statements and reports; the cancellation of the authorized capital so that "each and every increase needs shareholders' approval"; and the cancellation of the contingent capital provisions without replacement.

Eastland has further requested the appointment of a special auditor pursuant to review activities in respect of the management board's management of the company with regard all activities in connection with the cash capital increase of March 2008 in the total amount of EUR2 million ($A3.2 million) subscribed in its entirety by Mr Schötteldreier in five subscriptions and five payments and a range of other matters.

Eastland said it was "particularly concerned that, being the largest shareholder of the company, it does not have any representation on the Berlin Pharma supervisory board … [and] seeks full financial transparency and explanation and disclosure of a series of related party transactions relating to the issue of shares and the use of company funds".

Earlier this week Eastland said a review of its operations revealed a range of potential breeches of the Australian Securities and Investments Commission regulations and ASX guidelines (BD: Dec 8, 2009).

Eastland fell 0.1 cents or 1.7 percent to 5.7 cents.

UNIVERSAL BIOSENSORS.

Universal Biosensors says it has shipped its first commercial order of blood glucose strips under its master services and supply agreement with Johnson & Johnson's Lifescan.

The company said it had received the $US16 million ($A17.5 million) milestone payment under the agreement triggered on regulatory clearance of the blood glucose product.

Universal Biosensors was up four cents or 2.2 percent to $1.89.

AVEXA

Avexa says Johnson & Johnson's Tibotec has agreed to a four month extension of their option agreement on Avexa's HIV integrase inhibitor program (BD: Nov 5, 2009).

Avexa said Tibotec's exclusive option to enter into a research and licence arrangement would continue until March 2, 2010 and during this period the two companies would continue to review the program.

Avexa said that over the past year the two companies had been working collaboratively to evaluate compounds from the program.

If Tibotec exercises the option, the companies would enter negotiations for an exclusive research and licence agreement on the HIV integrase inhibitor program.

Avexa said it was optimizing a number of lead compound series towards the selection of lead molecules for preclinical testing.

Avexa fell half a cent or 3.1 percent to 15.5 cents with 1.4 million shares traded.

VIRAX HOLDINGS

Virax says it has applied to the US Patent and Trademark Office for a patent relating to the identification of patients most likely to respond to its HIV therapeutic vaccine VIR201.
Virax said the patent application is with collaborator Prof Martyn French from Royal Perth Hospital and was part of a worldwide application.
The company said the patent related to the identification of patients most likely to respond to VIR201 based on the mode of action of VIR201.
The company said it also differentiated VIR201 from other HIV vaccines designed to act purely through T-cells that have failed clinical testing.
Virax chief executive officer Dr Larry Ward said the patent filing "constitutes another plank in the VIR201 patent and development strategy".
"This patent will sit alongside the Co-X-Gene patents, the previously reported composition of matter patents for VIR201 and provide a patent estate that maximizes protection of VIR201," Dr Ward said.
"It will significantly extend the period of protection for the use of VIR201 and allow us to more effectively design future clinical trials by selecting patients most likely to respond to the vaccine," Dr Ward said.
Virax said the composition of matter patents had a period of exclusivity for VIR201 until 2019 in the US.
The company is also currently prosecuting patents relating to use of VIR201 in the context of patients discontinuing antiretroviral treatment, with a period of exclusivity until 2024 in Singapore with applications in other jurisdictions pending.
Virax was up 0.6 cents or 11.1 percent to six cents.

KARMELSONIX

Karmelsonix says it has signed Clear Sales Australia to market and distribute the Personal Wheezometer into retail pharmacies throughout Australia.
Karmelsonix was unchanged at 4.8 cents with 1.1 million shares traded.

SOLAGRAN

Solagran says it is not aware of any information that has not been announced which, if known, could be an explanation for recent trading in its securities.
The ASX said the company's share price fell 25.9 percent from 27 cents at the open of trading on December 9, 2009 to 20 cents on the same day, along with an increase in trading volumes.
Solagran provided the ASX with no meaningful answers to the standard questions other than saying it was in compliance with the listing rules, in particular listing rule 3.1 on transparency.
Solagran was up two cents or 8.7 percent at 25 cents with 1.3 million shares traded.