Biotech Daily

Tuesday March 2, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN:**
- SUNSHINE HEART UP 9%; IMPEDIMED DOWN 12%

*** BIONOMICS HIGH DOSE BNC210 'SAFE, TOLERABLE'**

*** 'CYTOPIA WORTH 7-TIMES WHAT WE PAID' –YM'S DAVID ALLAN**

*** EASTLAND REPORTS IRREGULARITIES TO ASIC, ASX**

*** CHEMGENEX MEETS ONCOLOGY COMMITTEE ON MARCH 22**

*** HALCYGEN'S 2nd STUDY SHOWS ANTI-FUNGAL BIOEQUIVALENCE**

*** VICTORIA PRIZE, FELLOWSHIPS OPEN FOR APPLICATIONS**

*** GIACONDA IRRITABLE BOWEL SYNDROME COLLABORATION**

MARKET REPORT

The Australian stock market climbed 0.33 percent on Tuesday March 2, 2010 with the S&P ASX 200 up 15.4 points to 4701.9 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and four were untraded.

Sunshine Heart was best, up 0.3 cents or 8.8 percent to 3.7 cents with 359,000 shares traded followed by Phosphagenics up 0.4 cents or 4.9 percent to 8.6 cents with 1.9 million shares traded.

Cellestis, Clinuvel and Patrys climbed more than three percent; Living Cell, Phylogica and Sirtex rose more than two percent; with Bionomics, Chemgenex, Optiscan and Resmed up more than one percent.

Impedimed led the falls, down nine cents or 12.3 percent to 64 cents with 36,500 shares traded, followed by Compumedics down 8.3 percent to 16.5 cents with 1,000 shares traded.

Viralytics fell 7.4 percent; Antisense and Starpharma fell four percent or more; Cathrx was down 3.6 percent; Heartware, LBT, Nanosonics, Novogen, Tissue Therapies and Universal Biosensors shed two percent or more; with Biota and Cellestis down more than one percent.

BIONOMICS

Bionomics says final results of its phase Ia clinical trial of BNC210 for anxiety show that it was generally safe and well-tolerated.

At the 2000mg high dose, Bionomics reported some patients with mild headaches and fatigue.

Bionomics chief executive officer Dr Deborah Rathjen said that on the four patients in the trial three were on the 2000mg dose of BNC210 and one on placebo.

Dr Rathjen said one patient on the drug reported a mild headache and one reported mild fatigue, with the third drug patient free of any adverse events.

Bionomics said the first stage of the trial, completed in October 2009, evaluated a dose range of 5mg to 1200mg in 32 healthy male volunteers (BD: Oct 27, 2009).

The company said that the second stage was conducted at the Royal Adelaide Hospital's Pain and Anaesthesia Research Clinic and was completed on schedule at the end of last year.

Bionomics said that evaluation of the safety and tolerability of BNC210 in stage two of the trial compared 2000mg of BNC210 with placebo and confirmed that BNC210 was safe and well tolerated at high dose levels.

In addition to safety and tolerability, stage two also involved an evaluation of blood cortisol levels, which showed that lower cortisol levels were observed in subjects receiving BNC210 compared to placebo.

As anxiety and stress lead to an elevation of cortisol, the observed change following BNC210 administration was consistent with anxiolytic activity and suggested that blood levels of the stress-related hormone might be useful as a biomarker of BNC210 activity.

Bionomics said the second stage of the trial also enabled an extension of pharmacokinetic data which indicated that a plateau of absorption of BNC210 was observed at doses between 600mg and 1200mg.

Dr Rathjen told Biotech Daily that the next trial would probably look at doses below 600mg due to the plateau of absorption at that level.

Professor of Clinical Pharmacology at the University of Adelaide and the principal investigator on the trial Prof Paul Rolan said the first clinical testing of BNC210 in man "has made important progress and under the conditions of this trial BNC210 has been shown to be safe and well tolerated".

"The most common reported side-effects which are possibly related to the drug were fatigue and headache, however these were quite mild," Prof Rolan said.

"The second stage of the phase Ia trial has yielded interesting data on blood cortisol levels," Prof Rolan said.

"Anxiety and stress lead to an elevation of cortisol and subjects treated with BNC210 showed lower levels of cortisol in their blood," Prof Rolan said.

"This finding, which will require further confirmation, may enable cortisol and potentially other neuroendocrine hormones to be used as biomarkers of BNC210 activity," he said.

Dr Rathjen said the trial "de-risked the BNC210 program with the data coming out of the study confirming that BNC210 is safe and has a pharmacokinetic profile which supports once a day administration".

"This trial has also given us an insight into biomarkers indicative of anxiety such as cortisol which will be followed up in the planned phase Ib clinical trial and which provide valuable information for the BNC210 licencing package," Dr Rathjen said.

BNC210 is being developed for the treatment of anxiety and co-morbid depression. The company said the anxiety market was worth up to $US15 billion worldwide and the global antidepressant market had sales of almost $US11 billion in 2008.

Bionomics was up half a cent or 1.7 percent to 30 cents.

YM BIOSCIENCES AUSTRALIA (FORMERLY CYTOPIA)

The chief executive officer and chairman of Canada's YM Biosciences David Allan says Cytopia's was worth "five, six or seven times what we paid for them had it been a US company".

In praising the Australian company he acquired for $14 million (BD: Oct 6, 7 2009), Mr Allan said that had Cytopia had access to the American markets he would not have been able to acquire it.

Mr Allan told an investor and media lunch hosted by Monsoon Communications in Melbourne that his company was in the business of drug development and bought drugs that had already been discovered. He said drug discovery belonged to government-funded institutions.

Mr Allan said YM Biosciences had a market capitalization of $US100 million and had $US35 million in the bank.

He said he was potentially interested in acquiring further Australian assets.

Mr Allan said YM Biosciences was developing the monoclonal antibody drug nimotuzumab which it acquired from the University of Havana and had special dispensation from US authorities to conduct US Food and Drug Administration-approved trials in the US, despite the US embargo on Cuba.

He said that unlike competitor drugs nimotuzumab did not cause painful rashes with treatment and had "the prospect of being the best in class" for head and neck cancers.

A second drug in the pipeline which is unlikely to be developed is Aerolf an inhaled fentanyl for pain, which he said was loved by patients and doctors, but hated by regulators because the dose could not be specified easily.

He said the acquisition of Cytopia and its two lead compounds CYT387 the Janus kinase (JAK) 1 and 2 in phase I/II trials for polycythemia rubra vera at the Mayo Clinic and the oral vascular disruption agent CYT997 were "very valuable assets".

Mr Allan credited Cytopia's founder and former chief scientific officer Dr Andrew Wilks for discovering the kinases in Melbourne. Dr Wilks also led the Cytopia team that discovered CYT997.

Mr Allan said that late last year Novartis and Eli Lilly acquired Janus kinases for up front fees of $US150 million and $US90 million, respectively.

He said that Cytopia's vascular disruption agent CYT997 was unique in that was orally available while all other vascular disruption agents were injectable only.

Mr Allan said the eight-member Australian team would continue because "we don't have the history of 997 and 387 in Toronto".

"It would be insane to lose that knowledge. We couldn't copy this," Mr Allan said.

Asked if he was interested in acquiring other Australian assets, Mr Allan said "Yes, we have spoken about that."

"We are an opportunistic small biotech. We will acquire molecules," Mr Allan said.

EASTLAND MEDICAL SYSTEMS

Eastland says the parties to an interim injunction relating to HC Berlin Pharma AG shares have provided undertakings not to dispose, transfer or encumber their shares.

Eastland said 1,526,600 HC Berlin Pharma shares were the subject of the action in the Supreme Court of Western Australia (BD: Dec 8, 2009).

Eastland said it had finalized an investigation into financial and regulatory irregularities between April 2007 to July 2009 and reported all relevant matters to the Australian Securities and Investments Commission and the ASX on February 25, 2010.

Eastland fell 1.2 cents or 16.2 percent to 6.2 cents with 1.2 million shares traded.

CHEMGENEX PHARMACEUTICALS

Chemgenex says the US Food and Drug Administration has rescheduled the previously postponed oncologic drugs advisory committee meeting to March 22, 2010.
The meeting was to be held on February 10, 2010, but Washington was snowed-in.
Prior to the meeting, the FDA published its concerns with the Chemgenex data, which the company dismissed at the time as part of the scientific debating process and provided no explanation for the FDA's criticism of the data (BD: Feb 9, 2010).
Today Chemgenex said the oncologic drugs advisory committee (ODAC) meeting would consider its application for Omapro or omacetaxine mepesuccinate for the treatment of adults with chronic myeloid leukemia who have failed prior therapy with imatinib and who have developed the Bcr-Abl T315I mutation.
The company said the independent panel of experts would review safety and efficacy data and make recommendations to the FDA concerning approval.
Chemgenex chief executive officer Dr Greg Collier said the meeting was "a significant milestone in the review process for Omapro, our team is well-prepared and we are looking forward to presenting to the ODAC panel".
Chemgenex was up one cent or 1.45 percent to 70 cents.

HALCYGEN PHARMACEUTICALS

Halcygen says its UK pharmacokinetic study has shown clinical bioequivalence of a half-dose of its anti-fungal drug SUBA-itraconazole with the market leader Sporanox.
Halcygen said that following a pre-registration meeting with the regulatory body, it intended to file for registration in the UK in August 2010 as a first step towards registration in the European Union.
Last year, the UK regulator required a further pharmacokinetic study to show that SUBA-itraconazole performed as well against European Sporanox (itraconazole) as it did against US Sporanox (BD: Aug 28, 2009).
Halcygen said the preliminary results showed that SUBA-Itraconazole given at a half dose to Sporanox was "clinically bioequivalent to Sporanox when given according to the prescribing information".
Halcygen said it would "seek further guidance from the [Medicines and Healthcare products Regulatory Agency] as to the sufficiency of the data for registration purposes with particular emphasis on what indications will be granted under the scope of a registration.
The company said that itraconazole was registered for use in indications including: onychomycosis candidosis, aspergillosis, histoplasmosis and cryptococcosis.
Halcygen chief executive officer Dr Roger Aston said he expected the results of this study would "allow us to file for registration of SUBA-itraconazole in the UK this year, potentially allowing Halcygen to receive income from first sales in 2011 … subject to regulatory authority review times and the appointment of an EU marketing and distribution partner".
"Licensing discussions to address marketing and distribution, whether regionally or globally, are currently under way with various partners," Dr Aston said.
Halcygen said its formulation had potentially greater safety than Sporanox.
Halcygen was up four cents or 6.8 percent to 62.5 cents.

VICTORIAN GOVERNMENT PRIZE, FELLOWSHIP

The Victorian Government has called for scientists, engineers and innovators to enter the 2010 Victoria Prize and Victoria Fellowships.

Innovation Minister Gavin Jennings said previous Victoria Prize and Victoria Fellowships winners had pioneered new ways of treating heart failure, stress and high blood pressure as well as the development of polymer technology which is now used to make bank notes in 22 countries.

“The Brumby Labor Government is taking action to support the innovative thinking which underpins much of modern society and is also an important driver of the Victorian economy that creates jobs for working families,” Mr Jennings said.

Mr Jennings said the $50,000 Victoria Prize and six $18,000 Victoria Fellowships have been awarded annually since 1998.

“Last year’s Victoria Prize was awarded to Prof Murray Esler who has pioneered new ways of treating heart failure, stress and high blood pressure and whose work continues to change the practice of medicine,” Mr Jennings said.

Other past recipients include Prof Peter Colman for his leading role at Commonwealth Scientific and Industrial Research Organisation in the discovery of the swine flu drug zanamivir (Relenza) and Prof David Solomon for his work on polymer technology, which includes the development of the world's first plastic bank note.

The Government media release said the $100,000 Anne & Eric Smorgon Memorial Award was awarded to the research institute supporting the work of the Victoria Prize recipient.

Winners of the 2010 Victoria Fellowships, whose study mission includes research undertaken in France, are also eligible to apply for a $5,000 AFAS Victoria Fellowship.

Applications close on April 14, 2010.

For more information and to apply visit http://www.business.vic.gov.au/vicprize.

GIACONDA

Giaconda says it has a collaborative research agreement with the Centre for Digestive Diseases for the research and development of Ibaconda for irritable bowel syndrome.

Giaconda said it owned “the patent and all the intellectual property in that treatment”.

The company said the Centre for Digestive Diseases was recognized as a leader in the research, diagnosis, and treatment of gastrointestinal conditions under the leadership of its founder and medical director, Prof Thomas Borody, Giaconda’s chief medical officer and major shareholder.

The company said the Centre would assume control and the cost of the ongoing research and development of Ibaconda and reimburse Giaconda for the research and development costs incurred since September 1, 2009.

Giaconda will be responsible for commercializing the Ibaconda treatment and if successful will pay the Centre 10 percent of those revenues.

Giaconda said irritable bowel syndrome was a major public health issue worldwide, whose cause is unknown, with a market of about $US5 billion a year.

Giaconda was untraded at five cents.