Biotech Daily

Tuesday August 4, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN; OPTISCAN UP 14%, BIONOMICS DOWN 14%**

*** IMMURON'S COW COLOSTRUM KILLS H1N1 'FLU VARIANT IN MICE**

*** BIOTRON COMPLETES TREATMENT IN PHASE Ib/IIa HEPATITIS C TRIAL**

*** PROGEN TAKES LEGAL ACTION AGAINST ALLEGED MEDIGEN CLIQUE**

*** HEALTHLINX: 'OVPLEX SUPERIOR TEST FOR OVARIAN CANCER'**

*** CORRECTION: NARHEX**

*** ITL APPOINTS CEO BRIAN ANDREWS MANAGING DIRECTOR**

*** AUSBIOTECH EXPECTS 1400 DELEGATES AT MELBOURNE CONFERENCE**

MARKET REPORT

The Australian stock market was up 1.08 percent on Tuesday August 4, 2009 with the S&P ASX 200 up 45.9 points to 4309.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and seven were untraded.

Optiscan was best for the second day in a row, up one cent or 14.3 percent to eight cents with 949,212 shares traded, followed by Nanosonics up 10.6 percent to 47 cents, and Novogen up 10 percent to 77 cents.

Genetic Technologies climbed 6.8 percent; Psivida was up 5.45 percent; Alchemia and Circadian were up three percent or more; Living Cell and Pharmaxis were up more than two percent; with Cathrx, Progen, Resmed and Universal Biosensors up more than one percent.

Bionomics led the falls, down 3.5 cents or 14.3 percent to 21 cents with 96,200 shares traded, with Tissue Therapies down three cents or 11.8 percent to 22.5 cents.

Starpharma and Viralytics lost more than six percent; Avexa and Clinuvel fell more than four percent; Mesoblast, Peplin, Phosphagenics and Sirtex were down more than three percent; Acrux and Chemgenex shed more than two percent; Biota and Heartware were down more than one percent; with Cellestis, CSL and Cochlear down less than one percent.

IMMURON

Immuron says a research collaboration has shown its cow colostrum polyclonal antibody product can stop and prevent infection for a variant of the H1N1 influenza virus.

Immuron said that in a treatment role in animal studies, the technology had shown it could stop an established infection with a single nasal application.

As a preventative, a single nasal application could prevent an influenza infection for a period of up to seven days, the company said.

Immuron said it expected to begin parallel human trials before June 2010 with a goal of creating a nasal spray or an oral application to be sold as an over the counter product.

In June the University of Melbourne was notified that it had been awarded an Australian Research Council Linkage Grant of $326,500 to continue research with Immuron into the treatment and prevention of Influenza (BD: Jun 5, 2009).

The company said that after peer review of the pre-clinical data generated jointly by Immuron and Prof Lorena Brown's laboratory at the University of Melbourne's Department of Microbiology and Immunology, the Australian Research Council approved the funding to assist in the next stage of the work.

Immuron said the team had shown that the concept of using Immuron's antibodies and antibody fragments to treat and prevent influenza showed "great promise to augment current vaccination and treatment strategies".

The company said the mouse models showed that production of high efficacy anti-viral antibodies (immunoglobulin G or IgG) in bovine colostrum could neutralize the infectivity of influenza virus. Antibodies against a laboratory strain of influenza virus known as PR8 were raised in cattle then harvested from the cow's colostrum.

The company said that the PR8 strain was a variant of the H1N1 serotype of human influenza and was used in a well-accepted laboratory mouse model for human influenza.

Immuron said cattle could be induced to produce high titre antibodies in kilogram amounts that effectively neutralized the virus and this meant that immunized cattle had "the potential to yield many thousands of doses of anti-influenza antibodies in the future".

Immuron said that bovine IgG preparations reduced the concentration of influenza virus in the upper and lower respiratory tract of mice.

The company said it tested the effectiveness of a single nasal treatment on mouse models of upper respiratory tract and lower respiratory tract infections with influenza virus.

The amount of influenza virus in the upper respiratory tract of the mice was measured to indicate the severity of disease and in most treatment groups "there was a significant reduction in virus load as far as five days after the single treatment".

"With higher treatment doses, the amount of virus dropped below detectable levels both in the lungs and in the nasal passages," the company said.

Immuron said the PR8 influenza virus caused significant clinical disease or death in mice. The mice were infected with virus and then treated with nasally-administered antibodies once the infection was established.

These experiments showed that the antibodies protected the mice from all clinical signs of infection, including death.

In a further study mice were given a protective dose of antibodies before they were infected some days later.

Immuron said that in this trial a single nasally-administered dose of the company's antibodies protected the mice from infection with virus for up to seven days.

The Immuron and University of Melbourne influenza program will trial several animal models over the next 12 months to gather data prior to human trials.

The company has extended its share plan to August 14, 2009 (BD: Jun 17, 2009).

Immuron was up half a cent or 13.9 percent to 4.1 cents.

BIOTRON

Biotron says it has completed the treatment stage of its phase Ib/IIa clinical trial of BIT225 for hepatitis C and expects results in about six to eight weeks.
Biotron said the trial was a placebo-controlled, randomized study of the safety, pharmacokinetics and antiviral activity of BIT225 in 18 patients with hepatitis C virus (HCV) infection in specialized clinical trial units in public hospitals in Queensland and New South Wales.
The company said the primary objective was to assess the safety and tolerability of BIT225 and the secondary objectives were to assess the pharmacokinetics of BIT225 as well as to assess the antiviral efficacy of BIT225 in these patients.
Biotron said the 18 hepatitis C virus-infected volunteers were grouped into three cohorts of six subjects.
All treated members of a cohort received the same drug dosage, receiving either 35 mg or 200 mg BIT225 twice daily for seven days, with one cohort receiving placebo.
Biotron said the data was blinded throughout the clinical phase of the study.
The company said that during the next six to eight weeks, the trial data would be assembled and reviewed by an independent data safety review committee to determine if BIT225 has met the primary safety end points and to analyze efficacy data.
Biotron said BIT225 was a first-in-class drug, targeting the p7 protein of HCV.
The company said that in the US alone, about four million people have hepatitis C with 2.7 million suffering from chronic infection.
Worldwide, 170 million people are infected with the virus which causes inflammation of the liver and could lead to fibrosis and cirrhosis, liver cancer and, ultimately, liver failure.
Existing drugs have limited effectiveness and toxicity issues, leaving a significant need for new therapies.
Biotron said the global market was $US3.0 billion, but is estimated that this market will expand to more than $US10.0 billion as safe, effective therapies enter the market.
Monotherapy with interferon-alpha and combination therapy of interferon-alpha and the ribonucleoside analog ribavirin were the two regimens approved as therapy for chronic hepatitis C, but they have limited effectiveness and are associated with side effects.
Biotron was unchanged at 12 cents.

PROGEN

Progen says it has instituted proceedings in the Supreme Court of Queensland against the shareholders alleging that acted in concert to control or influence the company's board.
Progen said it had taken action against Medigen Biotechnology Corporation, Tzu Liang Huang also known as James Huang, CCH Investment Corp, Lee Chuan Huang, Ya Wen Huang, Su-Hua Chuang, Pai-Mao Lin, Fu-Ying Wang, Fu Mei Wang, Joe Yeh-Chiao Lin, Heng Hsin Tang, Yung-Fong Lu, Lee Li Hsueh Yang, Fu-Chang Tsai, Chi-Liang Yang, Ho-Lung Wu and Kuo-Jan Wang.
Progen alleged the Respondents contravened section 606 of the Corporations Act 2001.
The company said the alleged contraventions related to the respondents having a greater than 20 percent interest in Progen's shares and "acting in concert for the purpose of controlling or influencing the composition of the board of Progen".
Progen is seeking an order restraining the respondents from further contravention of section 606 of the Corporations Act 2001 and further or alternatively, an order vesting all of the respondents' shareholdings in Progen in the Australian Securities and Investment Commission.
Progen was up one cent or 1.4 percent to 74 cents.

HEALTHLINX

Healthlinx says data from independent biostatisticians Emphron Informatics shows that its Ovplex test for ovarian cancer is superior to the standard CA125 test.

Healthlinx said the metrics of the diagnostic performance including measurement of the false positive rate and false negative rate for Ovplex and CA125 were estimated for a high-risk, pre-selected group of women with pelvic masses.

Healthlinx managing director Nick Gatsios told Biotech Daily that Emphron looked at data from 362 patient samples tested by Healthlinx and results from a separate CA125 retrospective study of 152 women admitted at Kasturba Hospital in Manipal India between January 1997 and August 1999.

Healthlinx said that the statistical analysis showed that if the Ovplex test was used in a population of women with pelvic masses it would reduce the number of misdiagnoses by more than 9,000 per 100,000 tests.

Ovplex said it had a 66 percent lowed false positive rate and a 56 percent lower false negative rate compared to the performance of CA125.

Mr Gatsios said the data showed the benefits of Ovplex in symptomatic women.

“The data clearly indicates that Ovplex is by far the most effective diagnostic for the detection of ovarian cancer in women with pelvic masses,” Mr Gatsios said.

“As we have discussed previously, the disease is treatable and survival rates increase dramatically with early detection,” Mr Gatsios said.

He said a second study of 1150 samples was planned to begin by the end of 2009.

“The original Ovplex panel along with two new novel biomarkers HTX005 and HTX010 are to be evaluated and assessed as to their potential inclusion in the future development of the Ovplex panel,” Mr Gatsios said.

“If this is successful and our target of greater than 97 percent diagnostic efficiency is reached, these numbers will improve even further,” he said.

Healthlinx was up one cent or 10.5 percent to 10.5 cents with 1.98 million shares traded.

CORRECTION: NARHEX LIFE SCIENCES

Narhex says its net operating cash burn for the three months to June 30, 2009 was not $125,000 as reported in yesterday’s edition but $48,000 with cash at the end of the quarter of $7,000.

As reported in Biotech Daily on July 17, 2009 Narhex has a $350,000 line of credit through a convertible note provided by executive chairman Dr Michael Cohen.

Biotech Daily apologizes for the error. The sub-editor has been warned.

Narhex is in a suspension from trading and has previously said it was preparing its accounts for relisting (BD: Jul 17, 2009).

ITL LTD

ITL has appointed chief executive officer Brian Andrews as managing director.

ITL said Mr Andrews was appointed chief executive officer on January 5, 2009 and had undertaken a thorough assessment of each of the company’s operating divisions and had been instrumental in implementing professional corporate controls and processes.

The company said Mr Andrews had more than 20 years experience in medical devices and had successfully marketed a broad range of technologies ranging from in vitro diagnostics to high technology capital equipment.

Mr Andrews holds a Bachelor of Science, Bachelor of Business and an MBA.

ITL was untraded at 7.9 cents.

AUSBIOTECH

Ausbiotech says its October 27-30, 2009 conference is expected to attract more than 1,400 delegates.

Ausbiotech says Australia's biotechnology sector "has matured into an internationally recognized industry, ranking sixth in the world in innovative biotechnologies".

The life sciences industry organization said Ausbiotech 2009 would bring together "the who's who of biotechnology from Australia and around the world in one world-class event".

Ausbiotech 2009 will be preceded by the inaugural Ausbiotech Australasian Life Sciences Investment Summit, an invitation-only, one-day event designed specifically to demonstrate to investors the high calibre of investment potential in Australia's biotechnology industry.

Ausbiotech said the conference would have a comprehensive program including sessions on four biotechnology streams: human health; medical technology; agriculture, industrial and food; and investment and business along with satellite events, a bio-industry exhibition and the business matching program, giving delegates access to the bio-partnering system to plan meetings with other delegates.

Ausbiotech said the 2008 business matching program resulted in 2,608 meeting requests and 1,226 confirmed meetings.

The conference presentations cover a range of topics including bio-pharmaceuticals post-global financial crisis, global regulatory challenges and opportunities, product development and regulatory aspects in Asia Pacific and changing business models and new financial opportunities and health technologies.

Ausbiotech said the key speakers for the conference would be Victoria's Governor Prof David de Kretser; National Australia Bank's chief economist Alan Oster; Baxter Healthcare vice-president of Asia-Pacific regulatory affairs and pharmacovigilance Dr Victoria Elegant; Commonwealth Scientific and Industrial Research Organisation's chief executive Dr Megan Clark; The president of Taiwan's Industrial Technology Research Institute Dr Johnsee Lee and the chief executive officer of Burrill & Co's Malaysian Life Sciences Fund Dr Ganesh Kishore.

The Australasian Life Sciences Investment Summit will be held on October 27, 2009 at the Melbourne Convention and Exhibition Centre, Clarendon Street, Melbourne, followed by the conference at the same venue from October 28 to 30, 2009.

For further information the conference website is at: http://www.ausbiotech2009.com.au/.