Biotech Daily

Wednesday September 8, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC TECHNO UP 8%; USCOM DOWN 41%**

*** MARC SINATRA'S BIOGUIDE: BIONOMICS – ALMOST PERFECT**

*** FERRET, MOUSE DATA BACK BIODIEM'S INFLUENZA VACCINE**

*** BLACKROCK TAKES 5% OF CSL**

*** AGENIX ACQUIRES CHINESE HEPATITIS B DRUG FOR $2.7m**

*** AGENIX RETURNS TO ASX TRADING ON FRIDAY**

*** HERSCHEL TAKES 13% OF CATHRX**

MARKET REPORT

The Australian stock market fell 0.79 percent on Wednesday September 8, 2010, with the ASX200 down 36 points to 4537.2 points.

Seven of the Biotech Daily Top 40 stocks were up, 15 fell, 14 traded unchanged and four were untraded.

Genetic Technologies was best, up 0.2 cents or 7.7 percent to 2.8 cents with 66,550 shares traded, followed by Cellestis up 4.2 percent to $2.50 with 85,816 shares traded.

Mesoblast and Virax climbed more than three percent; Patrys rose 2.3 percent; with Cochlear up 1.5 percent.

Uscom led the falls, down 14 cents or 41.2 percent to 20 cents with 5,000 shares traded, followed by Sunshine Heart down 10.3 percent to 2.6 cents with 500,000 shares traded.

Benitec and Immuron lost more than seven percent; Phosphagenics was down 6.2 percent; Acrux fell 3.2 percent; Clinuvel and Tissue Therapies shed more than two percent; with Alchemia, Biota, Chemgenex, Nanosonics and Resmed down more than one percent.

MARC SINATRA'S BIOGUIDE: BIONOMICS

Overview: Bionomics started life largely as a gene discovery and diagnostics company in 1999 but in 2003 it started a drug discovery program focused on influencing the GABA-A receptor in the hope of targeting indications such as epilepsy.

Today, Bionomics is all about drug discovery for cancer, anxiety, epilepsy and multiple sclerosis and has compounds in the clinic for two of these indications and has licenced the program for multiple sclerosis to Merck-Serono.

On the surface, Bionomics has made great strides in transforming itself into a drug development company, but what happens when you give the tyres a good kicking?

Financials: Market cap: $83 million; cash: $11.7 million; last quarter cash burn: $2.4 million.

Directors: Non-executive chairman, Chris Fullerton; chief executive officer, Dr Deborah Rathjen; non-executive directors, Dr Errol De Souza and Trevor Tappende.
Bionomics has a small, but strong board. A lot falls on the shoulders of Dr Rathjen and, given the range of activities, an additional board member is warranted. Someone with large pharmaceutical company drug development experience like Dr George Morstyn or Carlo Montagner would be perfect. Bionomics' management team is notably strong.

Products in Development: Bionomics drug development efforts are focused on five principle programs.

1) BNC105 – Cancer: BNC105 is a vascular disrupting agent, which acts by disrupting tumor blood vessels. BNC105 is thought to achieve this through an effect on tubulin and is also thought to have a direct cytotoxic effect on tumors. BNC105 has completed a phase I study for multiple cancers and is in phase II studies for renal cell cancer (RCC) and mesothelioma. Interim results from the RCC trial are due at the end of this year and from the mesothelioma trial in early 2011, with full data due from both trials in 2012.

2) BNC210 – Anxiety: BNC210 successfully completed a two-stage, phase I trial earlier this year. An additional phase I study is underway, looking at variables including the effect of food intake, stress hormone levels and other central nervous system parameters. Results from the food intake part of the study have shown a four-fold increase in blood levels of BNC210 when it is taken with food. A range of other data collected in the study is due next quarter. Bionomics also expects to initiate two phase Ib studies by the end of 2010. One study will look at the effect of BNC210 in healthy subjects in whom anxiety has been induced, while the other will look at its effect on the brain using electro-encephalographic measurements. Results from the phase Ib studies are expected in early and mid-2011.

3) Kv1.3 Blockers – Multiple Sclerosis: In mid-2008, Bionomics signed a development and licensing agreement with Merck-Serono, which paid Bionomics' $2 million up-front and agreed to fund all development activities in exchange for being able to select from a range of Kv1.3 potassium channel inhibitors developed by Bionomics. For each compound Merck-Serono selects, Bionomics may receive up to $US47 million in milestones plus a royalty on sales. Last May, this agreement was extended for one year.

4) BNO69 – Cancer: BNO69 is a discovery stage project of a potential target for anti-angiogenesis inhibitors. Screening for suitable small molecule inhibitors is underway.

5) GABA-A Agonists – Epilepsy: A discovery phase project, Bionomics has identified several compounds that can modulate the GABA-A receptor. Gamma-aminobutyric acid (GABA) receptors are the main inhibitory neurotransmitter in the central nervous system. Bionomics' testing of these compounds continues. This program commenced in 2003.

Significant Product Markets: The renal cell cancer market is large, with sales of $US2.2 billion of branded drugs in 2008. These sales are forecast to grow to $US6.5 billion in 2015, representing a growth rate of 16.8 percent.

The mesothelioma market is small and only worth pursuing as a market entry strategy via orphan drug status.

The anti-anxiety drug market, which covers a wide array of indications, had sales of $US4.5 billion in 2006. The market, however, has been forecast to shrink to $US2.6 billion by 2015 due to drugs coming off-patent.

There are not a lot of drugs in development specifically for any of these indications, although this doesn't rule out already approved drugs that might be seeking secondary indications.

Verdict: Bionomics has transitioned itself extremely well into a drug development company with two very solid projects and a nice licencing deal.

The only criticism I have of Bionomics is that they have made their desire to licence BNC105 after phase II trials and BNC210 after phase I trials too clear. Nothing is wrong with a licencing strategy kept in-house, but when it becomes public, two things happen. Firstly, would-be licencees know where you stand before you sit down at the table, weakening your negotiating position. Secondly, the clock starts ticking and interested parties will take note. Potential licencees will adjust their offer based on the time that has elapsed, while investors may lose faith, ultimately, killing even good projects. After Avexa with apricitabine, promising a deal "if we do just one more thing" isn't going to wash with people anymore.

However, aside from the fact that they have made their strategy public, everything else they are doing to secure a deal is perfect.

Bionomics is clearly in the elite group of Australian listed biotechnology companies.

Based on the value of comparable companies, I have given Bionomics a valuation of 38 cents per share.

Bionomics was unchanged at 29 cents.

Marc Sinatra's Bioguide
email: marc@biotechdaily.com.au

BIODIEM

Biodiem says preclinical research has shown significant advantages for its live attenuated influenza vaccine (LAIV) technology for H5N1 (avian) influenza.

Biodiem said two presentations at the Options for the Control of Influenza conference in Hong Kong at the weekend were co-authored by director and LAIV investigator Dr Larisa Rudenko.

The research showed that the live attenuated influenza vaccine technology provided greater protection compared to the inactivated vaccine against heterologous (related but not identical) virus shedding.

Biodiem said the cross-protection was important where there was a need to produce an effective vaccine for a virus such as the H5N1 which evolved quickly.

The company said four-fold higher local levels of immunoglobulin A in the nose following the administration of the LAIV helped explain an enhanced defence against influenza transmission in the upper respiratory tract.

Biodiem said a paper entitled 'Immunogenicity and cross-clade protective efficacy in ferrets of live-attenuated and inactivated vaccines prepared from an H5N1 live-attenuated reassortant vaccine candidate' was presented on September 4, 2010.

Biodiem said the LAIV vaccine in the ferret study was cell-based, not egg-based and cell-based manufacture of influenza vaccines was a new technology and important for ensuring adequate supply of vaccines for protection in the case of a pandemic.

The presentation reported on a comparative evaluation in ferrets of the immunogenicity and cross-protective efficacy of a cell-based manufactured live-attenuated influenza vaccine (LAIV) and an inactivated influenza vaccine (IIV).

Biodiem said that both the live and inactivated influenza vaccine candidates demonstrated immunogenicity and protection against homologous lethal H5N1 influenza virus infection in ferrets and provided a significant reduction in virus shedding and disease severity after heterologous H5N1 virus challenge.

The LAIV provided greater protection against heterologous virus shedding compared to the inactivated vaccine candidate and also induced higher immunoglobulin A antibody levels in nasal secretions.

A poster entitled 'Characterization of reverse genetics-derived cold-adapted influenza virus A/Leningrad/134/17/57 (H2N2) and its reassortants with H5N1 surface genes in a mouse model' was also presented at the conference.

Biodiem chief executive officer Julie Phillips said the company was "delighted to have this important research featured at an international conference".

"These ferret study results together with the mouse data showing protection, reinforce that our LAIV technology is a serious contender in the battle against influenza," Ms Phillips said.

"The H5N1 strain of influenza remains a key concern globally in terms of its ability to produce a serious pandemic," Ms Phillips said.

Biodiem was untraded at 15 cents.

CSL

The Blackrock Group has become a substantial shareholder in CSL with the acquisition of 27,497,024 shares or 5.00 percent of the company.

The multi-national Blackrock Group said it acquired its most recent parcel of 4,526,008 shares for $143,938,359 or an average price of $31.80 a share between May 1 and September 2010.

CSL fell 11 cents or 0.3 percent to $33.14 with 1.1 million shares traded.

AGENIX

Agenix has acquired a hepatitis B and HIV drug from China's Institute of Medicinal Biotechnology for RMB17 million ($A2.72 million).

Agenix said it had an exclusive agreement with the Institute, part of the Beijing-based Chinese Academy of Medical Sciences, to purchase, develop and commercialize AGX-1009, which was a patented, novel targeted pro-drug analog of an existing compound.

The company said the Institute was "the major state institution in China for the discovery and development of anti-infectious drugs".

Agenix said AGX-1009 was one of the drug candidates supported by the Chinese Government's state special funds for important newly-developed drugs.

The company said that preliminary pharmacodynamics, pharmacokinetics and toxicity studies, performed by the Institute, showed that AGX-1009 had strong inhibition against HIV and hepatitis B and had a low toxicity profile and high oral bio-availability.

Agenix said it would develop the drug for treatment of patients in China with chronic hepatitis B.

The company said patent for the compound ran until 2026 and the purchase price was payable in instalments, pending milestones.

Based on the expected performance of milestones, RMB6 million ($A960,000) would be payable over the first 12 months.

Agenix said it and the Institute of Medicinal Biotechnology would collaborate to complete the regulatory requirements for the new drug and to obtain the production licence for it.

Agenix said it would have the responsibility for commercializing AGX-1009 in China.

Agenix executive chairman Nicholas Weston said the pro-drug had the potential "to improve outcomes for seriously ill patients who have stopped responding to other treatments available for their condition".

"This agreement is demonstrative of the strong and deep relationships that Agenix enjoys in China and is a further step in the transformation of Agenix as it builds a portfolio of products for chronic infectious diseases in China," Mr Weston said.

AGX-1009 is an anti-Hepatitis B drug that belongs to a new class of drugs called nucleotide analogue reverse transcriptase inhibitors.

The closest competitor for AGX-1009 was expected to be GSK and Gilead's Tenofovir DF which obtained US Food and Drug Administration approval for hepatitis B in 2008 and could be approved by China's State Food and Drug Administration by 2014.

Agenix said the human body converted AGX-1009 into an active compound that worked by interfering with the function of an enzyme, a hepatitis B DNA polymerase, that was essential for the replication of hepatitis B.

Agenix last traded at 1.7 cents.

AGENIX

The ASX says Agenix will return to trading at 10am on September 10, 2010 "following lodgment of the company's financial report for the year ended June 30, 2010 and receipt of an announcement providing details of the company's current financial and operational position".

Agenix has been developing Thromboview for the detection of pulmonary embolisms and acquired interests in two Shanghai pharmaceutical companies.

The Chinese deal became mired in a range of problems (BD: Feb 14, Jun 6, 2007; Jul 24, 2008) at the same time that former chief executive officer and chief financial officer Neil Leggett misappropriated more than $4 million of the company's money (BD: Feb 18, May 18, 2010).

CATHRX

Herschel Asset Management has increased its substantial shareholding in Cathrx from 12,500,000 shares (8.72%) to 18,000,000 shares (12.56%).

Herschel said it acquired the 5,500,000 shares on September 6, 2010 for $771,694 or an average price of 14.03 cents a share.

Cathrx was unchanged at 18 cents.