Biotech Daily

Thursday August 7, 2008

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECHS UP: MESOBLAST UP 8%, CIRCADIAN DOWN 7%**

*** CEO INTERVIEW: BIONOMICS' DR DEBORAH RATHJEN**
- 'THIS IS JUST THE BEGINNING'

*** BIOTRON BEGINS HUMAN TRIALS OF HEPATITIS C INHIBITOR**

*** AVITA STRIKES DEALS FOR FUNHALER AND RECELL**

*** US PATENT GRANTED FOR USCOM'S OXYCOM DEVICE**

*** AGENIX CHAIRMAN RAVINDRAN GOVINDAN RESIGNS**

*** ANZ DIVESTS ALL OPES PRIME'S SOLAGRAN SHARES**

MARKET REPORT

The Australian stock market edged up 0.2 percent on Thursday August 7, 2008 with the All Ordinaries up 11.9 points to 5,030.0 points.

Sixteen of the Biotech Daily Top 40 stocks were up, five fell, 10 traded unchanged and nine were untraded.

Mesoblast was best, up 10 cents or 8.33 percent to $1.30 on moderate volumes, followed by Cathrx up five cents or 6.67 percent to 80 cents and Antisense up four cents or 6.06 percent to seven cents.

Cytopia and Ventracor climbed five percent or more; Chemgenex, Living Cell and Pharmaxis were up more than four percent; Psivida and Resmed were up more than three percent; Arana and Prana rose more than two percent; Alchemia, Biota, Universal Biosensors and Viralytics up more than one percent.

Circadian led the falls, down six cents or 7.41 percent to 75 cents with 7,000 shares traded, followed by Neuren down 6.67 percent to 8.4 cents.

Cellestis lost 4.68 percent; Cochlear shed 2.88 percent; with Avexa, CSL and Optiscan down more than one percent.

CEO INTERVIEW: BIONOMICS' DR DEBORAH RATHJEN

Bionomics chief executive officer Dr Deborah Rathjen may be slight of build but her sights are set high.

Dr Rathjen has taken a shell company with a board and $4 million but no staff and little value to a Top 20 company with a market capitalization of $75 million, multiple $50 million "big pharma" deals and a broad pipeline based on a small molecule discovery platform.

And according to Dr Rathjen, this is just the beginning.

Born in Broken Hill, Deborah was educated at North Broken Hill Primary School and following the family's move to Adelaide, matriculated from Seacombe High School in chemistry, biology, two maths and English, completing a Bachelor of Science (Hons) in immunology at Flinders University in 1978.

Her first job was as a research assistant to Prof Ian Chubb (now the vice chancellor of the Australian National University) at Flinders' Department of Human Physiology.

The then Deborah Evans married chemist David Rathjen and when he went to work for the Dow Group in Sydney in 1980, she found a job at the Commonwealth Scientific and Industrial Research Organisation, working with one of Australia's first private biotechnology companies, Bioclone, developing monoclonal antibodies .

"CSIRO were quick off the mark," Deborah says. "They developed test kits for measuring hormones and had one of the first monoclonal antibody test kits for pregnancy. That was when I decided I wanted to do a PhD in monoclonal antibodies and then I became a post-doc student."

In 1988 Peptech founder Geoff Grigg "rang up and said 'I have a job for you'" and Deborah set up Peptech's anti-tumor necrosis factor (TNF) program.

She says one of the programs was a around polyunsaturated fatty acids for a range of indications including anti-inflammatory disease and pain.

"It would have made a good biotech company," she says.

She held a range of different jobs within the company ending up in business development and licencing out

In 1989 she was granted a patent for 'TNF binding ligands' a way of describing how TNF worked and how it could be modified by monoclonal antibodies.

"Both Johnson & Johnson's Remicade and BASF's Humira infringed.

"The case ran from 1997 when the European Union said it would grant the patent to Peptech to 2002."

In June 2000 she was headhunted for the top job at Bionomics by one of the major executive search companies, which in other circumstances would have been wonderful news.

But the Rathjen family was in the middle of renovating the family home in Sydney and one of the conditions of the job was relocating to Adelaide. With three young children a family pact was agreed and Deborah spent seven months commuting from her Monday to Friday job in Adelaide to be with her family in Sydney for weekends.

"I'm just a typical suburban mum," Deborah laughs, noting the extensive travel.

"It was a virtual company with no staff, some very early stage intellectual property in epilepsy genetics from Adelaide's Women's and Children's Hospital and the University of Melbourne. The IP today is unrecognizable by comparison.

"It was like being presented with a blank canvas. The board had about $4.5 million which was not a lot of money but enough to have a runway.

"In the first six weeks I raised $5 million and in the second six weeks located a path and the wherewithal for the facility in Thebarton. It was a very productive first three months and then I started hiring people."

Deborah says that in that flurry of activity she wrote a business plan which is “pretty much what you see today” and built a company that “wasn’t just genomics but drug discovery for therapeutics.

Bionomics started with validated drug targets in angiogenesis and the first deal was a co-development with Genmab.

“In February 2006 we converted it to a straightforward licence to Genmab with an upfront fee of half a million dollars, $1 million in preclinical milestones this year and more to go.”

“In 2005 we decided that building a company through partnerships and organic growth alone wouldn’t give the value increase we were looking for,” Deborah says.

Bionomics acquired the Strasbourg-based Neurofit in March 2005 and Melbourne’s Iliad in July 2005. Iliad was a Start-Up Australia-backed chemistry company.

“Everything you see in Bionomics dates from then. The chemistry is all the one platform.

Deborah presents one of Bionomics investor brochures which has the pipeline pointing vertically instead of across the page.

“The foundation is Bionomics’ biology, cancer vasculature and ion channel, the drugs in development are the walls and the roof is our ‘Multicore’ chemistry – the way we go about our chemistry. “With Multicore we can change the molecular scaffold and it gives us many more combinations of compounds to make.”

From this small molecule platform the company has BNC105 a cytotoxic vascular disruption agent for solid tumors, BNC210 for anxiety and Kv1.3 a target for multiple sclerosis partnered with Merck Serono.

“Bionomics has a broad range of compounds that are highly selective, orally active and suppression the symptoms of multiple sclerosis in animal models,” Deborah says. “Merck Serono can select an undisclosed number of compounds and for each one we get $US47 million in milestone payments.”

Deborah says BNC105 is in phase I dose escalation trials and the recruitment of up to 30 patients is “on track” and expected to be competed by the end of 2008 with results by June 2009 and possibly earlier.

But the planning for the phase II trial is already underway.

“We know what’s happening [in the phase I trial], we’re encouraged by the enthusiasm of the clinicians in the trial,” Deborah says.

She says the company’s business model is to licence-out compounds and partner for later stage development, with different compounds having different points for licencing and partnering.

Deborah says the company wants to licence BNC210 for anxiety after phase I and BNC105 after it has been taken to phase II.

She says her contract is up for renewal and asked where she sees herself going in the future says: “My thinking is only Bionomics.”

“Getting 105 established in its phase II program is going to be a very important milestone next year, along with cementing the relationship with Merck Serono and getting our anxiety compound into the clinic next year.”

Asked what Bionomics can do that no one else can, the slightly built Dr Deborah Rathjen from Broken Hill via Adelaide doesn’t hesitate:

“Bionomics is making small molecule drugs that fill market needs and they are substantial markets in the pharmaceutical industry, like anxiety. You don’t get much bigger than that!”

Dr Rathjen laughs as she packs up to be taken to her next meeting.

Bionomics was unchanged at 32 cents.

BIOTRON

Biotron says it has started an Australian phase Ib/IIa clinical trial of BIT225 in hepatitis C virus-infected patients.

Biotron said a phase I clinical trial for BIT225 was successfully completed in uninfected volunteers in 2007 and the phase Ib/IIa clinical trial in Sydney would be the first assessment of the drug in hepatitis C virus-infected patients.

Biotron said the phase Ib/IIa clinical trial was a blinded, placebo-controlled, randomized study of the safety, pharmacokinetics and antiviral activity of BIT225 in patients with hepatitis C virus infection.

Biotron said the primary objective was to assess the safety and tolerability of BIT225, given twice daily at a dosage of 35 mg and 200 mg, for 14 consecutive days.

The secondary objectives were to assess the pharmacokinetics of BIT225 as well as to assess the antiviral efficacy of BIT225 at a dosage of 35 mg and 200 mg, in these patients.

Eighteen patients, males and females (of non-childbearing potential), aged 18 to 55 years with chronic hepatitis C virus infection will receive one of two dose levels of BIT225 or placebo on a random selection basis.

Biotron expects the trial will be completed by the end of 2008.

Biotron managing director Dr Michelle Miller said hepatitis C was a significant health problem, with a large percentage of patients failing current treatments.

Dr Miller said BIT225 “may offer an alternative for those patients”.

“The initiation of clinical testing of Biotron’s [hepatitis C virus] inhibitor in infected patients is a major milestone for the company,” Dr Miller said.

Biotron said BIT225 was an orally administered, antiviral compound targeting the p7 protein of hepatitis C virus, demonstrating good antiviral activity in surrogate models of hepatitis C virus infection and had been shown to be highly synergistic with current leading therapies for this disease.

The company said hepatitis C virus caused inflammation of the liver, which could lead to fibrosis and cirrhosis, liver cancer and ultimately liver failure.

Existing drugs for hepatitis C virus have limited effectiveness and toxicity issues, leaving a significant need for new therapies, Biotron said.

Biotron said the worldwide market was $US3.0 billion, but was estimated to expand to more than $US10.0 billion as safe, effective therapies enter the market.

The company said monotherapy with interferon-α and combination therapy with interferon-α and the ribonucleoside analogue ribavirin are the two approved therapies for chronic hepatitis C.

Biotron said treatment with interferon-α alone, or in combination with ribavirin, has limited effectiveness with frequent side effects, injectable administration and poor patient tolerance and adherence.

Patients can experience influenza-like symptoms, fatigue and depression.

Ribavirin can be problematic for patients with pre-existing anemia, kidney problems or heart disease.

Bioton said four million people in the US have been infected with hepatitis C with 2.7 million suffering from chronic infection. Worldwide, 170 million people are infected with the virus.

Biotron was unchanged at 15 cents.

AVITA MEDICAL

Avita Medical says it has Mexican regulatory approval for its Recell wounds treatment and has signed a Greek distribution agreement for its Funhaler paediatric incentive spacer.

Avita said the $40,000 deal with Greek distributor D Analytica would the Funhaler supplied to Greek pharmacies, healthcare providers and hospitals.

The company said the Athens based D Analytica had longstanding relationships with paediatric specialists, hospitals, private clinics and major chain pharmacies

Avita said D Analytica would launch the Funhaler asthma spacer in September in advance of the Northern Hemisphere winter respiratory season and had begun pre-marketing activities at paediatric health care congresses.

Avita's chief executive Officer Dr William Dolphin said asthma was "a significant health care problem for Greek children and adolescents".

"In the last 10 years Greece, with a population of approximately 11.2 million, has experienced a dramatic increase in diagnosed asthma and corresponding sales of bronchodilators," Dr Dolphin said.

"We are anticipating a high level of acceptance and uptake of the Funhaler product," he said.

Avita Medical said the Funhaler incentive asthma spacer was designed for the paediatric market, with auditory and visual incentives to encourage children to comply with their medication plan and has been clinically demonstrated to improve compliance to prescribed medication and increase proper inhalation technique.

The Funhaler has Conformitée Européenne (CE) Mark, US Federal Drug Administration clearance and Australian Therapeutic Goods Administration registration.

Avita said it has received regulatory approval from the Mexico Secretaria de Salud for the sale and marketing of Recell.

The company said Recell was a stand-alone, rapid cell harvesting device that enables surgeons to treat skin defects using the patient's own cells that are collected during surgery.

The surgeon can prepare a small quantity of cells within 30 minutes on site rather than having to send a biopsy to the laboratory, the company said.

Avita said Recell has been designed for use in a wide variety of plastic, reconstructive and cosmetic procedures and was gaining acceptance in a number of indications including Vitiligo, a common skin pigmentation disease.

Avita said it worked closely with distributor, Productos, Equipos y Servicios de Salud Especializados SA (PESSE) in securing Mexican regulatory approval.

Avita said PESSE was focused on the burns and plastic surgery markets in Mexico and was among the leading providers of specialty products for the hospitals, burns and plastic surgery clinics.

"The Mexican regulatory process is complex and time consuming and Recell approval by Salud is a significant milestone for Avita Medical," Dr Dolphin said.

Avita said Recell was approved for sale in Australia, Brazil, Canada, Chile, Croatia, European Union, Hong Kong, Israel, Japan, Malaysia, Mexico, New Zealand, Norway, Singapore, South Africa, Switzerland and Turkey.

The company is in the process of securing US Food and Drug Administration approval for sale in the US.

Avita fell 0.8 cents or eight percent to 9.2 cents.

USCOM

Uscom says it has a US patent for its Oxycom device for the non-invasive measure of oxygen in blood.
The company said Oxycom was the first device which gave accurate and non-invasive measurement of oxygen delivery as an alternative to the current invasive methods.
The patent author and Uscom chairman Rob Phillips said oxygen delivery was “a critical measure of the effectiveness of the circulation and reflects the severity of cardiovascular disease”.
“The new Oxycom product, currently in testing, provides this information non-invasively and beat to beat; a first in the world of physiology and medicine,” Mr Phillips said.
Uscom said Oxycom provided real-time beat-to-beat information across multiple parameters of cardiac function and provided advanced trending capabilities, allowing clinicians to accurately quantify the effect of treatment.
Uscom said the device was suited to paediatrics, intensive care and emergency medicine and anaesthesia where it is critical to monitor changes in cardiac output as fluids and drugs are administered.
The company has regulatory approval for sale of the Uscom 1A monitor in Australia, Europe and Asian and has regulatory clearance for the US.
Uscom was untraded at 26 cents.

AGENIX

Agenix says chairman Ravindran Govindan has resigned from the board.
Agenix said Mr Govindan resigned for health reasons.
The company’s China acquisition recently stalled when it failed to receive a waiver for the sale of a local pharmaceutical company from the four percent shareholder, who is also the landlord (see Biotech Daily, July 24, 2008).
Agenix chief executive officer Dr Stephen Phua has taken direct responsibility for the Shanghai based operation.
No replacement director was disclosed by the company.
Agenix was unchanged at two cents.

SOLAGRAN

Solagran says it has been told by the Australia and New Zealand Banking Group that all of its Opes Prime shares have been sold by the bank.
The ANZ Bank acquired the Solagran securities following the collapse of Opes Prime Stockbroking.
Solagran said the ANZ Bank no longer held any of its shares.
On April 11, 2008 the Bank held 56,107,515 ordinary shares (42.6%) and 10,132,865 partly paid shares (21.0%) of Solagran (see Biotech Daily, April 11, 2008).
Solagran climbed 12 cents or 41.38 percent to 41 cents with 7.7 million shares traded.