



Biotech Daily

Tuesday August 26, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: VENTRACOR UP 14%, STEM CELL DOWN 21%**
- * **NEURODISCOVERY: 'TRIAL SHOWS NSL-101 EFFECTIVE IN PAIN RELIEF'**
- * **AVEXA TAKES GREATER CONTROL OF LEAD DRUG APRICITABINE**
- * **MONASH UNI'S 'NANO-TROJAN-HORSE' TO AID NUTRITION**
- * **MEDICAL THERAPIES' CSO, DIRECTOR RESIGNS; US PATENT GRANTED**
- * **BIOPROSPECT BIOEFFECTIVE CHOOK TRIAL 'NOT SIGNIFICANT'**
- * **FOUR WOMEN SCIENTISTS WIN \$20K L'ORÉAL FELLOWSHIPS**
- * **BIO-MELBOURNE NETWORK: MANAGING A MULTI-PRODUCT PIPELINE**
- * **ANTISENSE EGM BACKS SHARE ISSUE, DIRECTORS' OPTIONS**
- * **VICTORIA COLLEGE OF PHARMACY BECOMES MONASH FACULTY**
- * **AUSBIOTECH'S AUGUST BIO-BEERS**

MARKET REPORT

The Australian stock market slipped 0.2 percent on Tuesday August 26, 2008 with the All Ordinaries down 7.8 points to 5,082.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and seven were untraded.

Ventracor was best, up three cents or 13.64 percent to 25 cents with 1.1 million shares traded, followed by Cathrx up 10.67 percent to 83 cents.

Viralytics climbed 7.84 percent; Clinuvel was up 6.35 percent; Agenix and Avexa were up five percent or more; Novogen was up 4.29 percent; Arana and Pharmaxis rose more than two percent; with Progen, Resmed and Universal Biosensors up more than one percent.

Stem Cell Sciences led the falls, down six cents or 21.43 percent to 22 cents on small volumes, followed by Circadian down 7.61 percent to 85 cents.

Acrux and Living Cell lost more than five percent; Impedimed and Starpharma fell more than four percent; Heartware was down 3.23 percent; Cellestis, Neuren, Phylogica and Prana shed more than two percent; with Chemgenex and Phosphagenics down more than one percent.

NEURODISCOVERY

Neurodiscovery says one its two phase IIa clinical trials has shown NSL-101 to be equivalent to commercially available anaesthetic for dental surgery.

Neurodiscovery said NSL-101 “was highly effective in the treatment of pain associated with root planing and scaling, a painful procedure used to combat periodontitis”.

A parallel clinical trial for the treatment of post-operative pain caused by the extraction of impacted third molars or ‘wisdom teeth’ was unable to clearly demonstrate NSL-101’s effects due to unexpected confounding factors.

This study was unable to evaluate the analgesic efficacy of NSL-101 compared with placebo in patients after the extraction of one or more impacted wisdom teeth.

Neurodiscovery said the duration of the local anaesthetic used during surgery was longer than expected, “thus potentially masking any analgesic effects of NSL-101 and compromising the outcome of the study”.

Neurodiscovery said the second study was designed to ensure that patients would not experience severe pain at any time and the company said NSL-101 was found to be well tolerated.

The first study was a double-blind, randomized controlled trial evaluating the analgesic efficacy, anti-inflammatory activity and safety of NSL-101 gel compared with a 5% local anaesthetic in a periodontological procedure of scaling and root planning.

Neurodiscovery said no adverse events attributed to the use of NSL-101 or anaesthetic gel were reported and NSL-101 produced numerically superior analgesia compared to 5% anesthetic gel, but the difference was not statistically significant.

Neurodiscovery said the periodontitis study compared the analgesic efficacy and safety of NSL-101 gel with a local anesthetic, which is the gold standard for pain prevention during scaling and root planning.

This procedure was used to treat moderate to severe periodontitis and was typically associated with significant pain.

The company said NSL-101 was highly effective and well tolerated.

“It was found to be equally effective as the local anaesthetic gel and no adverse effects were reported,” Neurodiscovery said.

Neurodiscovery said the results from the periodontitis trial demonstrated that NSL-101 was an effective analgesic preparation and this proof-of-concept data “significantly enhances the value of this clinical asset”.

The company said the results had led to a patent filing describing the preparation, formulation and use of NSL-101.

Neurodiscovery said it was seeking an appropriate out-licencing and/or collaborative partner who would receive the rights to market NSL-101.

Neurodiscovery chairman Dr Mark Treherne said that there were “significant commercial opportunities for new additions to toothpastes, ulcer gels, toothache remedies, as well as creams and ointments for stings and grazes”.

“NSL-101 may also have future commercial applications following minor cosmetic procedures,” Dr Treherne said.

The trial of 50 patients aged 18-55 years with moderate to severe periodontitis undergoing scaling and root planning procedure was conducted at Cayetano Heredia University in Lima, Peru.

Neurodiscovery fell one cent or 10 percent to nine cents.

[AVEXA](#)

Avexa says it has renegotiated its licence arrangements with Shire for its apricitabine (ATC) program, reducing royalties and obligations to Shire.

Avexa will issue Shire with \$US5 million of new equity, equal to 18.6 million shares, which would increase Shire's holding in Avexa to 11.1 percent.

Avexa said the new shares were to be held in escrow for 12 months unless there was a change of ownership.

Other terms and conditions of this renegotiation remained confidential, but Avexa's chief executive officer Dr Julian Chick told Biotech Daily that Shire would benefit from increased equity in Avexa rather than a royalty stream from apricitabine.

"There will be very small trailing royalties, dropping significantly to single digits, with the removal of a number of obligations to Shire," Dr Chick said.

"It just makes everything easier," Dr Chick said.

Avexa said in a media release it believed "that as a result of the renegotiation a substantially greater proportion of the future commercial value of ATC could accrue for the benefit of Avexa shareholders through a reduction of sales royalties and removal of future milestone payments".

The media release said that since Avexa licenced apricitabine from Shire in March 2005, Avexa progressively enhanced "the drug's commercialization strategy, as evidenced by the renegotiation of the North American rights to ATC in January 2007, giving Avexa full worldwide rights, as well as the current renegotiated licence terms giving Avexa greater potential ownership of the drug".

Dr Chick said the changes gave Avexa greater ownership of apricitabine and allowed the company to explore all avenues for apricitabine and the subsequent commercialization of the product.

"The company will be in a stronger position with ATC," Dr Chick said.

Avexa said the phase III studies for ATC continued to progress well with 100 sites initiated in North America, Europe, Israel, Australia and South America.

The company said it continued to progress preparation for additional countries and sites to be initiated when required for the second of the phase III trials.

Avexa climbed 1.5 cents or five percent to 30.5 cents with 1.0 million shares traded.

[MONASH UNIVERSITY](#)

Monash University researchers have designed a nano-sized "trojan horse" particle so that antioxidants can be better absorbed.

A Monash University media release said Dr Ken Ng and Dr Ian Larson from the University's Faculty of Pharmacy and Pharmaceutical Sciences (formerly the Victorian College of Pharmacy – see below) have designed a nanoparticle, one thousandth the thickness of human hair that protects antioxidants from being destroyed in the gut, improving the likelihood of being absorbed in the digestive tract.

Monash University said antioxidants are known to neutralize the harmful effect of free radicals and other reactive chemical species generated in the body and are thought to promote better health.

The University said that a human's own antioxidant defence was sufficient, but in high-risk individuals, such as those with a poor diet or those at risk of developing atherosclerosis, diabetes or Alzheimer's disease, a nutritional source of antioxidants was required.

Dr Larson said orally delivered antioxidants were easily destroyed by acids and enzymes in the human body, with only a small percentage of what is consumed actually being absorbed.

The solution is to design a tiny sponge-like chitosan biopolymeric nanoparticle as a protective vehicle for antioxidants.

Chitosan is a natural substance found in crab shells.

"Antioxidants sit within this tiny trojan horse, protecting it from attack from digestive juices in the stomach," Dr Larson said.

"Once in the small intestine the nanoparticle gets sticky and bonds to the intestinal wall," he said.

"It then leaks its contents directly into the intestinal cells, which allows them to be absorbed directly into the blood stream," Dr Larson said.

Dr Larson said that "by mastering this technique, drugs and supplements also vulnerable to the digestive process can be better absorbed by the human body".

The research project will proceed to trials early in 2009.

Dr Ng said although the research was still in its early stages, the longer term aim of the project would be to include similarly treated nanoparticles into food items, similar to adding omega-3 to bread or milk.

"For catechins – the class of antioxidants under examination and among the most potent dietary antioxidants -- only between 0.1 and 1.1 per cent of the amount consumed makes it into our blood," Dr Ng said

"If we can improve that rate, the benefits are enormous," he said.

MEDICAL THERAPIES

Medical Therapies says director and chief scientific officer Dr Stephanie Williams has resigned, effective immediately.

The company said Dr Williams was appointed earlier this year "on a temporary basis to assist with the company's transformation during the process of the acquisition of the Midkine intellectual property portfolio" (see Biotech Daily; February 15, 2008).

Medical Therapies said the Midkine acquisition was settled on July 3, 2008 and a strategic business plan for the new portfolio had been completed.

The company said it would actively look for suitably qualified directors.

In February, Medical Therapies said Dr Williams had worked extensively as a scientist and as an advocate for health and medical research and "has invaluable cancer research experience and a strong industry network".

Separately, the US Patent and Trademark Office has granted Medical Therapies' patent application entitled 'Agents Comprising Midkine or an Inhibitor Thereof as Active Ingredient'.

Medical Therapies said it was "a significant therapeutic patent" in its portfolio relating to the treatment of inflammatory diseases by Midkine and/or its inhibitors and also covers key disease interests in the company's product development plan.

The company said the patent had been granted and issued in other key territories including Europe and Australia, providing broad global coverage for the treatment of inflammatory diseases.

Medical Therapies said Midkine modulated biological functions such as apoptosis, cell growth and cell migration and as a consequence it presents an important therapeutic and diagnostic target.

The company said it held 26 patent and patent application families of the global 51 patents existing in relation to Midkine.

Medical Therapies says it "has the largest portfolio globally of intellectual property around Midkine and anti-midkine compounds".

Medical Therapies fell 1.5 cents or 25 percent to 4.5 cents.

BIOPROSPECT. SOLAGRAN

Bioprospect says a trial of 300 chickens on Solagran's Bioeffective A showed "no significant differences between the groups".

Bioprospect said the birds were in six groups assessing different doses of the pine needle extract Bioeffective A against a control group and a group receiving antibiotics.

"At 21 days of age, there were no significant differences between the groups, although birds on some of the diets containing Bioeffective A were heavier than the control groups and had similar results to the antibiotic treatment groups," a Bioprospect media release said.

The company described the results as "encouraging".

The trial looked at feed consumption, live weight gain and feed conversion ratio with assessment over a 25 day period post hatching, using commercially available diets.

Six Bioeffective dose rates were evaluated in conjunction with a control diet with no additives and a diet that used zinc bacitracin as the antibiotic.

Bioprospect said it was common to see a low-dose antibiotic like zinc bacitracin placed in the diet mix as insurance against infection and to improve the respective feed conversion of food into meat.

The company said this was "an important factor for chicken producers taking into account the high cost of feed and production in general" and there was an opportunity to find a suitable replacement for the use of antibiotics in this case.

Bioprospect said it intended to test Bioeffective A at lower rates over larger numbers of chickens to confirm the findings from the screening trial.

The company said it would assess potential effects in direct pathogen controls in vitro and in vivo as well as attempt to establish an acceptable daily intake level to permit further trials in production animals on a larger scale as well as investigate testing in other types of production animals such as pigs and cattle, attract suitable collaborators involved in commercial animal feed production and evaluate a second product called Bioeffective I. Bioprospect said the chickens actively consumed feed that contained the Bioeffective indicating that there was no rejection based on taste and texture.

The trial was conducted at the University of New England School of Environmental and Rural Science in Armidale, NSW.

Bioprospect climbed 0.1 cents or 4.76 percent to 2.2 cents.

Solagran climbed 0.5 cents or 0.95 percent to 53 cents with 1.7 million shares traded.

L'ORÉAL FELLOWSHIPS

The winners of the 2008 L'Oréal Women in Science Fellowships include research on nano-safety, fighting viruses and autoimmune diseases.

A media release from L'Oréal said the four fellows were chosen from 213 applicants for the calibre of their science and will receive \$20,000 each tonight from the Governor of Victoria Prof David de Kretser and L'Oréal chief executive officer Mark Tucker.

The 2008 L'Oréal Australia For Women in Science Fellows are:

The University of Melbourne's Dr Amanda Barnard to create computational tools to predict the behavior of nanoparticles in the environment;

Monash University protein chemist Dr Natalie Borg to analyze protein crystals with synchrotron light, to discover how bodies mount a defence when attacked by a virus;

Walter and Eliza Hall Institute immunologist Dr Erica Cretney to pursue a group of T-cells that play a role in controlling inflammation and in auto-immune diseases; and

University of New South Wales' evolutionary biologist Dr Angela Moles who has visited 75 ecosystems to understand how and why plants vary.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says multi-product portfolio development requires well planned management strategies.

The Network's recently appointed chief executive officer Michelle Gallaher says most biotechnology companies "manage, or are already in the process of building, a product portfolio backed by a robust research engine or pathway that can deliver new leads over time".

"For these biotechs and their executives, it is critical that they have the necessary specialist skills and planning to manage a multi-product development strategy," Ms Gallaher said.

The September 9, 2008 Bio-Breakfast is sponsored by Phosphagenics and will hear from two experts examining the strategic issues and management skills that executives need to develop the commercial strategies required for a successful multi-product development. Phosphagenics executive director of research and development Dr Esra Ogru will introduce the management strategies that should be considered by a company and its board to develop a multi-product pipeline.

Dr Ogru will discuss these requirements using the Phosphagenics' experience as an example.

Dr Ogru will also talk about the key commercialization considerations in product selection for a technology platform, the targeting of product pipeline prospects, as well as product management and out-licensing strategies for different stages of the development cycle. Griffith Hack principal of life sciences intellectual property Wayne Condon will present on the legal elements of multi-product growth strategies to drive commercial growth.

Mr Condon will look at the importance of a strong intellectual property position, as well as effective out-licencing strategies to support commercial development plans.

The Bio-Breakfast will be held at the Supper Room, Melbourne Town Hall, Swanston St, Melbourne on September 9, 2008, with registration from 7.15 am and presentations commencing at 8am.

For more details visit www.biomelbourne.org or call Shane Hickey on +613 9650 8800.

ANTISENSE

Antisense shareholders have overwhelmingly supported the prior issue of shares and the grant of options to five directors.

Antisense shareholders approved the prior issue of 37,500,000 shares and 18,750,000 options to Firebird Global Master Fund and Circadian Technologies through subsidiary Polychip Pharmaceuticals as well as to Canadian merchant bank Powerone Capital Markets (see Biotech Daily, April 16 and July 22, 2008).

The also approved the issue of 3,000,000 options at a nil exercise price vested in three tranches to Antisense chief executive officer Mark Diamond and issue of \$15,000 worth of free options to each of Robert Moses, Prof George Werther, Dr Chris Belyea and Prof Graham Mitchell.

Antisense said all but one resolution was passed with more than 180 million proxy votes cast in favor and up to 3.8 million proxy votes against the proposals.

The issue of shares was passed by 75,878,497 proxy votes in favor with 1,473,530 proxy votes against.

Antisense was unchanged at 6.7 cents.

VICTORIA COLLEGE OF PHARMACY, MONASH UNIVERSITY

Monash University faculty, the 127 year old Victorian College of Pharmacy, has become the Faculty of Pharmacy and Pharmaceutical Sciences.

Faculty dean Prof Bill Charman said the name change, the Parkville campus's \$45 million redevelopment and new research building was a step forward.

"The new name clearly articulates our vision as an eminent Australian faculty with a breadth of expertise that enables us to deliver on all aspects of pharmacy and pharmaceutical sciences," Prof Charman said.

A Monash University media release said that to maintain a tangible link to its past the faculty has retained the name of its alumni arm, the Victorian College of Pharmacy Foundation.

"Having proudly honored our past achievements, there was a need to better communicate the faculty's present day position and future focus, pharmacy and pharmaceutical sciences," said Prof Charman.

Originally the school of the Pharmaceutical Society of Victoria, the Victorian College of Pharmacy merged with Monash University in 1992.

A Monash University media release said the faculty now delivered a variety of undergraduate and postgraduate courses in the area of pharmacy and pharmaceutical sciences to more than 1200 students.

The media release said that academic and research staff at the faculty collaborate with partners including pharmaceutical and biotechnology companies, research institutes and universities.

"Our new name better reflects the faculty's distinct position within the healthcare, pharmaceutical and biotechnology sectors," Prof Charman said.

AUSBIOTECH

Ausbiotech will hold its third Bio-Beers informal get-together this Thursday, August 28, 2008.

Ausbiotech says the event "is gaining momentum" with industry personnel catching-up with colleagues and Ausbiotech staff.

The evening will be held at The Trust, 405-411 Flinders La, Melbourne, from 6pm to 9pm.