

Biotech Daily

Friday February 26, 2010

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: BONE UP 7%; GENETIC TECHNO DOWN 15%
- * WEHI'S \$1.75m WINNERS DR SCOTT, DR BLEWITT FOCUS ON CANCER
- * ONE COMPONENT HALTS NANOSONICS TROPHON DELIVERY
- * BIODIEM EXPANDS PIPELINE WITH NEW INDICATIONS
- * NHMRC GRANTS MENTAL HEALTH INSTITUTE \$14m FOR ALZHEIMER'S.
- * BIOMD TO RAISE \$1.3m IN UNDERWRITTEN 2-for-3 OPTIONS ISSUE
- * AVITA H1 REVENUE UP 22% TO \$2m, LOSS DOWN 55%
- * NEURODISCOVERY 'SERVICES' H1 PROFIT ON REVENUE UP 7% TO \$1.5m
- * BLACKROCK TAKES 5% OF CSL
- * BIO-MELBOURNE WORKSHOPS 'TIPS AND TRAPS' OF LICENCING

MARKET REPORT

The Australian stock market climbed 0.95 percent on Friday February 26, 2010 with the S&P ASX 200 up 43.6 points to 4637.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and seven were untraded.

Bone was best, up one cent or 7.1 percent to 15 cents with 14,881 shares traded, followed by Benitec up 5.3 percent to four cents with 430,959 shares traded.

Phosphagenics climbed 3.9 percent; Alchemia, Antisense, Chemgenex and Universal Biosensors rose more than two percent; with Genera, LBT, Mesoblast and Psivida up more than one percent.

Genetic Technologies led the falls, down 0.6 cents or 15.4 percent to 3.3 cents with 180,000 shares traded, followed by Nanosonics down 8.8 percent to 52 cents with 1.2 million shares traded.

Patrys and QRX lost more than six percent; Cellmid, Sirtex and Viralytics fell more than three percent; Starpharma and Sunshine Heart shed more than two percent; with Biota, Circadian, Clinuvel and Heartware down more than one percent.

WALTER AND ELIZA HALL INSTITUTE

The Walter and Eliza Hall Institute says two of its "outstanding female scientists … have been awarded research fellowships worth \$1.75 million for their cancer research". The Institute said its inaugural five-year Cory Fellowship was awarded to Dr Clare Scott and the inaugural five-year Dyson Fellowship was awarded to Dr Marnie Blewitt. The Institute said that Nobel Prize winner for medicine Prof Elizabeth Blackburn announced Dr Scott and Dr Blewitt as the successful fellowship recipients, last night. Walter and Eliza Hall Institute director Prof Doug Hilton said Dr Scott and Dr Blewitt were worthy fellowship recipients, being "stellar examples of researchers who were making important scientific discoveries and had the ability and drive to lead a research team". "The Cory and Dyson Fellowships have made it possible for Marnie and Clare to spend more of the next five years concentrating on their science and less on applying annually for research funding," Prof Hilton said.

Prof Hilton said the two researchers were appointed WEHI laboratory heads on January 1, 2010 which would "go some way to redressing the imbalance that exists in Australian science where there is a gross under-representation of women at senior levels". The Cory Fellowship, named after Prof Suzanne Cory, the institute's first female director, was established last year to encourage outstanding female scientists to take up leadership positions in medical research. The five year fellowship is open to Australian women wanting their first opportunity to lead a laboratory at the Walter and Eliza Hall Institute. A media release from the Institute said Dr Scott was also a medical oncologist at the Royal Melbourne Hospital and was trying to identify the genes and biological pathways that stop the body from efficiently killing lymphoma and cancer cells, including breast and ovarian cancer cells.

"Many new cancer drugs designed to target the biology of the cancer in question cause cancer cells to stop growing but do not kill them well enough, allowing the tumors to recur," Dr Scott said. "I hope to harness the built-in killing machinery that exists within cells to improve outcomes for cancer patients."

The Institute said Dr Scott had a particular interest in ovarian cancer and, through the fellowship, would design a program of epithelial ovarian cancer research to be undertaken over the next five years.

WEHI said Dr Blewitt was studying epigenetics, a relatively new field of research into how cells know which of its genes should be active at any given time.

John Dyson, who co-manages the Dyson Bequest with Rose Gilder, said the Dyson Fellowship was awarded to Dr Blewitt because of the enormous potential for her research to overhaul our understanding of the human genome.

"This is research that could help explain how cancer develops in some people and could ultimately lead to the development of new treatments," Mr Dyson said.

Dr Blewitt said the Fellowship would allow her to finish establishing a viral short hairpin RNA (shRNA) library to identify new epigenetic modifiers in the mammalian genome. "Epigenetics refers to the modifications or the 'tags' that are present on the DNA and which help to tell cells when to switch something on and use it and when to turn something off," Dr Blewitt said. "One thing that happens in cancer is genes that control cell growth are switched on such that too much of the protein that promotes cell growth is produced, and the cells keep multiplying and don't die, which can lead to a tumor."

"Sometimes that over-production of protein is due to epigenetics; the normal gene is still there but the epigenetic modifications have changed and so the gene is on or off when it shouldn't be," Dr Blewitt said. "If we find some epigenetic modifiers that have a role in cancer that information could help develop new treatments for cancer," Dr Blewitt said.

NANOSONICS

Nanosonics says it identified "a component of a sub-assembly which is currently not meeting Nanosonics' exacting quality assurance standards".

Nanosonics said that in its commercial scale-up of production of the Trophon EPR ultrasound probe disinfection system it found the component error.

Nanosonics' chief financial officer Chris Grundy told Biotech Daily that the component was causing the system "to report a failed cycle when in fact it hasn't failed".

Mr Grundy said the company had halted commercial delivery while its staff evaluated and validated replacement components.

Mr Grundy said there was "nothing wrong with safety of efficacy" and that an earlier batch of the components from the same supplier had no problems.

He was unable to say when he expected production to resume.

In a media release, Nanosonics said the component was "supplied by an external overseas vendor and is not manufactured by Nanosonics directly".

The company said the supplier had undertaken to provide updated components for Nanosonics' assessment in the near term.

In parallel, Nanosonics has sourced several alternative high-quality and functionally similar replacement components, which are currently being evaluated and assessed for suitability, the company said.

Nanosonics said it had produced a significant quantity of Trophon devices in the current quarter which await release for sale under its company's quality assurance system. The company said it was continuing to pre-assemble Trophon EPR units while awaiting the availability and validation of a replacement component.

Nanosonics said it was targeting "near-term resolution of the impact of the component and related issues on the recommencement of the scale-up of production, subject to validation".

The Trophon EPR device continues to meet its full performance specifications, including safety and efficacy, even with the variable performance of the component in question, the company said.

It is anticipated that validated replacement components will, in fact, lead to greater production efficiency and enhanced reliability in the field.

Nanosonics said more than 100 Trophon EPR units were currently installed and in regular use in ultrasound clinics in Australia, New Zealand and France.

Customer feedback is very positive for the Trophon EPR and the value that it brings to the ultrasound examination process, Nanosonics said.

Customer acceptance continues to build, with key opinion leaders internationally validating and supporting the uptake of the device.

The company said it had significant demand in Australia and New Zealand, with the previously reported "in-principle" order from a major imaging company progressing to a final rollout schedule in Australia.

In New Zealand, the District Health Boards in Auckland have moved to standardize the Trophon system as a product of choice, Nanosonics said.

Nanosonics said it was evaluating a number of options to scale increased production capability of the Trophon EPR device.

The Company is actively recruiting to resource both the growth of Trophon EPR product range and, in parallel, to accelerate the development of a number of other commercial applications of the company's nano-nebulant platform technology.

Nanosonics fell five cents or 8.8 percent to 52 cents with 1.2 million shares traded.

BIODIEM

Biodiem has reviewed its project portfolio and will pursue new indications for two of its existing compounds with LAIV as a viral vector and BDM-I as an anti-microbial. Biodiem has been developing its live attenuated influenza virus technology (LAIV) primarily for influenza, but has been working on the virus as a facilitator in vaccine design and specifically as a viral vector to deliver antigens or epitopes in vaccines to elicit an immune response in the vaccine recipient.

The company said the resulting vaccines can target a wide range of diseases depending on the choice of antigen or epitope which is delivered.

Biodiem said many viruses were being used as viral vectors in vaccine research programs and were in development for cancers and infectious diseases.

Examples of viral vectors include pox viruses such as fowlpox, vaccinia and canarypox, and adenovirus and adeno-associated viruses.

Biodiem said it would investigate whether the potential advantages of its technology, including expected safety and strong immunogenicity would position the LAIV "as a strong platform technology which could be used to assist development of a broad range of vaccines for infectious diseases and cancers".

The company said the plan would require experiments to support the potential of this use and grant funding would be sought from the Commercialisation Australia program. Biodiem said the resulting data would be used to offer research licences to vaccine developers across a range of different research areas and successful vaccines would provide a royalty stream.

The long history of safe use of the Biodiem LAIV strains could provide a distinct advantage and a sound commercial basis for exploring further this new business opportunity, the company said.

Biodiem said the LAIV influenza vaccine had the advantage of needle-free intranasal administration and was being developed by licencee Nobilon/Merck using a cell-based manufacturing system, which has brought the LAIV technology to a phase II proof of concept clinical trial in Europe, with results expected later this year.

Biodiem chief executive officer Julie Phillips told Biotech Daily the second new development was with BDM-I which had been previously investigated for use as a growth promoter in the agricultural sector, but in vitro research at the Royal Melbourne Institute of Technology showed potential value as an antimicrobial, effective against human disease-causing microbes including, gram positive and gram negative bacteria and fungi.

"The clinical applications are quite broad in a market where there are very poor treatments for life-threatening infections, especially bacterial and fungal infections," Ms Phillips said. Biodiem said that the anti-infectives market had grown significantly in recent years and was \$US70 billion in 2006-'07 with the entry of new products worldwide.

The company said resistance was a growing problem for many antimicrobials and it would begin with a small number of confirmatory activity studies for BDM-I, testing in animal models of infectious diseases.

Biodiem said that pending the results of these studies it would approach potential licencees to complete the development work and clinical trials.

These licences can be issued for BDM-I development in different disease areas and provide BDM-I with an earlier revenue stream. We will also continue exploration in-house of the use of BDM-I in specific areas for example, invasive and superficial fungal diseases where high unmet medical need exists, Biodiem said.

Biodiem said work would continue on BDM-E for retinal disease at Cambridge and Monash Universities.

Biodiem was untraded at 22 cents.

MENTAL HEALTH RESEARCH INSTITUTE, PRANA BIOTECHNOLOGY

Melbourne's Mental Health Research Institute has been granted \$14.2 million of the National Health and Medical Research Council's \$150 million for health and medical research.

The Mental Health Research Institute said its executive director Prof Colin Masters and his team at the Institute and the University of Melbourne were working to develop an effective treatment for Alzheimer's disease as well as searching for a biomarker that would allow the diagnosis of the disease long before symptoms appear.

"We already know that substantial damage has been done to the brain before people display symptoms of Alzheimer's disease," Prof Masters said.

"So it is important that we find a means to diagnose the illness early enough for any drug that is developed to be effective," Prof Masters said.

The MHRI said the grant would allow Prof Masters' team focus their research on treatment and early diagnosis based on understanding the underlying cause of the illness

A central problem in Alzheimer's disease research is to understand how the nerve cells deteriorate as the disease progresses. The accumulation of the amyloid beta protein was the principal marker of the disease, but the exact form of the molecule which causes damage to the nerve cell synapses was yet to be identified, the MHRI said.

"We anticipate this research will result in a greater understanding of how the amyloid beta protein behaves in Alzheimer's disease. This information can then be utilised to design disease specific drug-based therapies," Prof Masters said.

The MHRI said the grant would also assist researchers advance understanding of the mechanism of a novel class of compound which includes Prana Biotechnology's PBT2, a drug currently undergoing clinical trials for Alzheimer's disease.

Prof Masters said the grant would "accelerate the pace of our research and gives us a real chance of developing a drug that will significantly slow the progress of the disease". Prana was unchanged at 15 cents.

<u>BIOMD</u>

Biomd hopes to raise \$1.3 million through a pro-rata non-renounceable issue of two new options for every three shares held at 1.5 cents per option.

Biomd said the issue was fully underwritten by Bell Potter Securities.

The company said the rights issue was replacing the capital raising initiative approved by shareholders at the extraordinary general meeting on December 10, 2009, to allow all eligible shareholders on the record date of March 3, 2010 to participate. Biomd was up 0.9 cents or 21.95 percent to five cents.

AVITA MEDICAL

Avita's revenue from sales of products was up 22 percent to \$2,024,350 for the six months to December 31, 2009, reducing its loss 55 percent to \$1,315,438.

Avita said the revenue primarily came from sales of its Recell wound treatment and its Breath-A-Tech respiratory devices, as well as grant income.

No dividend will be paid.

The company said its net tangible assets per share was down 26.8 percent to 5.2 cents compared to the previous corresponding period.

Diluted loss per share was 1.34 cents compared to 3.17 cents in the six months to December 31, 2008.

Avita was unchanged at 14.5 cents.

NEURODISCOVERY

Neurodiscovery says its net profit after tax for the six months to December 31, 2009 was \$257,042 compared to a loss of \$164,493 for the previous corresponding period. Neurodiscovery said revenue was up seven percent to \$1,474,345 of which \$1,461,241 came from its "specialist services business".

The company's executive director David McAuliffe was unavailable at the time of publication to detail that specialist services, but Neurodiscovery said in its Appendix 4D half-year report that it was "a neuroscience service provider".

Diluted earnings per share was 0.42 cents compared to the previous corresponding period's loss of 0.29 cents.

Neurodiscovery was untraded at 4.2 cents.

<u>CSL</u>

Blackrock Investment Management has become a substantial shareholder in CSL with a holding of 29,760,986 shares or 5.1 percent.

Blackrock, representing sister companies in several countries including the US, Japan and the UK, traded shares between October 22, 2009 and February 23, 2010.

The substantial shareholder notice said Blackrock traded mainly in small parcels of shares but some trades ranged up to \$5 million or \$7 million in a single order.

CSL fell seven cents or 0.2 percent to \$34.39 with 5.2 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network will hold a workshop on the "tips and traps" of licencing and valuations as integral parts of biotechnology business strategies.

The Bio-Melbourne Network said its March 16, 2010 workshop would be conducted by Davies Collison Cave partner Rodney DeBoos and Victoria Government co-chief scientist and Foursight Associates principal Dr Graham Mitchell.

Bio-Melbourne Network chief executive officer Michelle Gallaher said that for many companies "the decision of when to licence and what makes a profitable and amicable licencing arrangement are crucial to get right".

The Network's Bio-Workshop is entitled 'Licensing and valuation intensive - Tips and Traps for the biotechnology executive'.

Mr DeBoos and Dr Mitchell will give expert advice, practical examples and share their experiences.

The half-day workshop will focus on why licencing makes business sense, what constitutes the necessary homework for a licence, what return should be expected from licencing and how licencing has been affected during the "global financial crisis".

The Bio-Workshop will be held at Davies Collison Cave, 1 Nicholson St, Melbourne with registration at 8.45am for a 9am start and concludes at 12.30pm followed by a light lunch. For more information go to: <u>http://www.biomelbourne.org/events/view/114</u> or call Anita Petris on +613 9650 8800 or email: <u>apetris@biomelbourne.org</u>.

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