



Biotech Daily

Thursday June 12, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: LIVING CELL UP 7%, AGENIX DOWN 21.5%**
- * **IMPEDIMED: BIOIMPEDANCE BEST TOOL FOR LYMPHOEDEMA**
- * **PHARMAXIS COMPLETES 12-MONTH PHASE III SAFETY EXTENSION**
- * **PETER MAC SHOWS DENOSUMAB IMPROVES GIANT CELL TUMORS**
- * **VICTORIA GOVERNMENT CREATES BIONET ASIA PACIFIC OFFICE**
- * **IM MEDICAL FINALISES SIGMA INTELLIHEART PHARMACY ROLLOUT**
- * **KARMELSONIX SIGNS MONITOR DISTRIBUTION FOR CHINA, BENELUX**
- * **ROCKEY SELLS HANGOVER PILLS TO CHINA**
- * **RITRACT RETRACTS FROM BIOTECH TO MINING**

MARKET REPORT

The Australian stock market tumbled again on Thursday June 12, 2008 with the All Ordinaries down 128.7 points or 2.3 percent to 5,433.2 points.

Three of the Biotech Daily Top 40 stocks were up, 23 fell, nine were unchanged and five were untraded.

Living Cell was best, up two cents or 7.41 percent to 29 cents on small volumes, followed by Clinuvel up 2.82 percent to 36.5 cents and Arana up one cent to \$1.075.

Agenix led the falls, down 1.4 cents or 21.54 percent to 5.1 cents, followed by Sunshine Heart down 21.43 percent to 5.5 cents, Stem Cell down 14.29 percent to 30 cents and Cytopia down 13.73 cents to 22 cents.

Bionomics, Mesoblast and Optiscan lost more than eight percent; Starpharma and Ventracor were down more than seven percent; Avexa, Cochlear, Peplin and Progen fell more than five percent; Pharmaxis and Phosphagenics fell more than four percent; Antisense and Polartech were down more than three percent; CSL and Heartware shed more than two percent; with Acrux, Chemgenex, Circadian and Universal Biosensors down more than one percent.

IMPEDIMED

Impedimed says a study of 300 Australian women diagnosed with breast cancer has found bioimpedance spectroscopy the most direct, accurate and reliable method for assessment and diagnosis of secondary lymphoedema.

The article in Lymphology 41 (March 2008) pp18-28 is entitled 'Lymphodema Secondary to Breast Cancer: How Choice of Measure Influences Diagnosis, Prevalence and Identifiable Risk Factors'.

The principal researcher for the study conducted by the Queensland University of Technology, Dr Sandra Hayes, said it examined how the choice of measure influences diagnosis, prevalence and identifiable risk factors in developing lymphoedema secondary to breast cancer.

Dr Hayes said bioimpedance spectroscopy was a direct measure of extracellular fluid and therefore lymphoedema.

Impedimed's medical devices use bioimpedance spectroscopy to detect lymphoedema.

"Other common diagnostic methods, such as circumferences or water displacement, assess limb size rather than fluid and changes in size may not always be causally related to lymphoedema," Dr Hayes said.

The study is one of the first Australian studies to compare the diagnostic effectiveness of bioimpedance spectroscopy in Australian women suffering from lymphoedema and compared bioimpedance spectroscopy with the indirect diagnostic methods of sum of arm circumference and self-examination.

"The problem with other diagnostic methods is that the medical practitioner does not know that lymphoedema exists until it manifests visible symptoms," Dr Hayes said.

She said 20 percent (2,500) of the 11,000 Australian women diagnosed with breast cancer each year developed secondary lymphoedema and early diagnosis was "a critical first step in the process of developing an effective treatment regime for lymphoedema sufferers".

"With 70 to 80 per cent of women who develop lymphoedema after breast cancer presenting within the first 12 months, we need to know how to diagnose and assess effectively in order to be able to intervene in a timely manner with the most appropriate treatment regime," she said.

ImpediMed chief executive officer Greg Brown said the QUT study reinforced recent findings of the US National Institutes of Health, National Naval Medical Center and George Mason University study, which found preoperative assessment of breast cancer patients for subclinical lymphoedema enabled clinicians to establish a baseline to enable the early diagnosis and successful treatment of the debilitating condition.

"With more and more people surviving cancer, emphasis will increasingly be focused on quality of life for cancer survivors," Mr Brown said.

Mr Brown referred to a statement made by the European Cancer Organisation last week which said that cancer survivors were living "in limbo" with unmet needs for care.

One gap in patient care recognized by the organization was in relation to the symptoms experienced by lymphoedema sufferers, especially chronic swelling caused by the failure of lymph glands to drain properly and psychosocial problems including depression and anxiety, Mr Brown said.

Separately, Impedimed said it was preparing for the official opening of its San Diego building by Queensland Premier Anna Bligh on June 17, 2008, associated with the BIO 2008 conference.

The facility has space for manufacturing as well as corporate offices for regulatory matters, quality assurance, sales, business development and instrument development. Impedimed was untraded at 70 cents.

PHARMAXIS

Pharmaxis has completed its 12 month phase III clinical trial evaluating the safety of Bronchitol in 100 subjects with bronchiectasis.

Pharmaxis said the 12 month treatment period was an open label extension to a three month efficacy trial which has already reported, showing that Bronchitol improved quality of life and mucus clearance (see Biotech Daily; August 29, 2007).

The company said the objective of the open label extension was to determine the adverse event profile of Bronchitol following prolonged use.

Following statistical analysis, the results from this second phase of the trial will be reported in July 2008.

Pharmaxis chief executive officer Dr Alan Robertson said following receipt of the study report, Pharmaxis intends filing its first marketing application in Australia for Bronchitol next quarter.

"We are receiving strong demand to continue treatment after participation in the trial has concluded and, where possible, we make this available," Dr Robertson said.

Bronchitol is being developed as a twice daily inhalation therapy for people with the incurable lung condition bronchiectasis.

Bronchiectasis is an incurable, degenerative and chronic lung condition that makes breathing difficult through excessive mucus build up in the lungs.

Pharmaxis fell 7.5 cents or 4.73 percent to \$1.51.

PETER MACCALLUM CANCER CENTRE

A clinical trial of denosumab for giant cell bone tumors led by Melbourne's Peter MacCallum Cancer Centre has shown "substantial improvements" in patients with bone cancer.

In a media release Victoria's Innovation Minister Gavin Jennings said Victoria was an international leader in cancer research.

He said the success of this treatment was an example of the research accelerated by the Victorian Centre for Functional Genomics.

Study leader and head of the Peter MacCallum Centre's Sarcoma Genomics and Genetics Laboratory Dr David Thomas said that interim results of the international trial had shown that 87 percent of patients treated with denosumab had significant improvement in their giant cell bone tumors after 25 weeks.

"The results achieved demonstrate the power of modern genomics in quickly developing new and effective cancer therapies," Dr Thomas said.

"The clinical trial arose from genetic research on bone cancers in 2005 which had shown giant cell tumors have an unusually high expression of certain genes," Dr Thomas said.

"One of these is the gene encoding a protein called RANKL which is involved in normal bone function.

"With colleagues from US pharmaceutical company Amgen Inc the study made use of an antibody developed by Amgen that targeted the RANKL protein and which was being tested for other clinical uses.

"Because of this we were able to move rapidly to use the molecular information from the genomics studies on this type of cancer to test a new treatment," Dr Thomas said.

Mr Jennings said the Victorian Government had provided \$483,900 towards the Victorian Centre for Functional Genomics total cost of \$974,300.

Dr Thomas presented the denosumab study findings in Chicago on May 31, 2008 at the meeting of the American Society of Clinical Oncology.

VICTORIA GOVERNMENT

The Victorian Government will provide \$190,000 to establish the Melbourne-based secretariat of Bionet Asia Pacific.

A media release said the Government grant was “positioning Melbourne and Victoria as the true biotechnology leader in the Asia Pacific region”.

Victorian Innovation Minister Gavin Jennings announced the funding before departing for BIO 2008 in San Diego with more than 150 Victorian science professionals.

The \$190,000 is intended to cover office costs at Ausbiotech in Malvern, Victoria and staff for two years.

“The Brumby Government is taking action to support Victorian innovation and this initiative driven by Ausbiotech places Victoria in a regional leadership position,” Mr Jennings said.

“The BIO 2008 delegation will alert global investors and companies to the gains they can make through Victoria’s involvement with Bionet Asia Pacific.

“The network enables us to strengthen our partnerships with Asian companies and governments and position Victoria as a conduit for US and European countries trying to access Asia-Pacific markets,” Mr Jennings said.

The media release said that as part of its goal of becoming a worldwide top five biotechnology location, the Victorian Government was hosting a forum on June 16 and sponsoring the “innovation corridor” at BIO 2008.

Victoria’s biotechnology sector is valued at more than \$21 billion and the state’s biotechnology companies have secured deals worth more than \$4 billion over the past three years, the Government media release said.

IM Medical

IM Medical will sell its Intelliheart cardiac risk assessment tests through Sigma Pharmaceuticals.

Describing Sigma as “one of Australia’s biggest retail health networks” IM Medical said the company would sell Intelliheart tests “in hundreds of Amcal Max , Amcal and Guardian pharmacies around Australia”.

IM Medical chief executive officer Tommas Bonvino said the agreement was “a significant milestone in IM Medical’s commercialisation strategy for Intelliheart”.

“The alliance combines IM Medical’s risk assessment technology leadership with the powerful brands and marketing power of Sigma,” Mr Bonvino said. “This combination will make preventative medicine a reality for more people”.

“Cardiovascular disease is Australia’s number one health issue measured by deaths and health costs.

“Much of it can be prevented,” Mr Bonvino said. “The first step is measuring risk and that it where Intelliheart comes in.”

Sales through the Sigma network are expected to begin through more than 200 pharmacies in Victoria in July, with other States following in the next few months.

IM Medical said Intelliheart was a non-invasive cardiac risk assessment test which takes a number of measurements for doctors to analyze and measure cardiac risk.

Sigma will have the right to produce and market other health and heart-related products under the Intelliheart brand.

The agreement follows a pilot program in pharmacies where consumer acceptance was tested and demonstrated.

IM Medical climbed as high as 3.2 cents before closing down 0.6 cents or 21.43 percent to 2.2 cents with 97.2 million shares traded

KARMELSONIX

Karmelsonix will sell its Pulmotrack respiratory monitor to the Benelux countries as well as China and Taiwan.

Karmelsonix has agreements with Accuramed of Belgium to distribute Pulmotrack in Belgium, The Netherlands and Luxembourg and with the Progressive Group to distribute the monitor in China and Taiwan.

Both distributors will purchase the product from Karmelsonix for resale.

The agreements were accompanied by initial sales of Pulmotrack units to both distributors.

Karmelsonix climbed 0.2 cents or 2.04 percent to 10 cents.

ROCKEBY

Rockeby has sold 623,000 Pepp hangover remedy tablets through Sandoz China.

Rockeby chief executive Dr Sze Wee Tan said sales of the tablet confirmed its popularity in Singapore and China.

Sandoz is marketing Pepp as a food product in more than 1600 pharmacy outlets in the coastal cities of Guangdong, Shenzhen, Beijing and Shanghai.

Rockeby said Pepp was a natural enzyme-based health supplement containing alcohol dehydrogenase, manufactured from a bio-fermentation process.

The company said it had been "clinically proven to be able to reduce alcohol levels and hangover symptoms".

Rockeby was unchanged at one cent.

RITRACT

RTL Corporation (formerly Ritract) is apparently changing from a biotechnology company to a mining services company.

RTL said it would acquire 100 percent of the intellectual property, assets and rights to manufacture and market a specialized underground agitator for the mining sector known as the Mine Mixer from Every Day Mine Services.

Subject to RTL shareholder approval, the company will issue 200 million performance shares in three classes to Every Day Mine Services.

RTL has sufficient cash reserves to continue work on the Ritract safety device as well as being able to progress the Mine Mixers opportunity.

A spokesman for RTL said the safety device would not be a high priority for the company.

Rittract fell 0.1 cents or 5.56 percent to 1.7 cents with 11.5 million shares traded.