



Biotech Daily

Wednesday July 21, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: IMPEDIMED UP 21%; CELLMID DOWN 8%**
- * **EDITORIAL: TAXPAYER GRANTS AND DISCLOSURE**
- * **TGA APPROVES 'WORLD FIRST' MESOBLAST STEM CELL SUPPLY**
- * **PHARMAXIS REPORT EXPLAINS BRONCHITOL TRIAL RESULTS**
- * **CAPITAL GROUP CLIENTS REDUCE FURTHER 1% IN COCHLEAR**
- * **US SPRINGTREE TAKES 5% OF NEUREN**
- * **EASTLAND APPOINTS STEPHEN CARTER CONSULTANT**
- * **ANTISENSE LOSES JOINT COMPANY SECRETARY KATE PLUMRIDGE**

MARKET REPORT

The Australian stock market climbed 0.21 percent on Wednesday July 21, 2010 with the S&P ASX 200 up 9.1 points to 4412.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and four were untraded.

Impedimed was best, up 11 cents or 20.6 percent to 64.5 cents with 46,800 shares traded, followed by Mesoblast up 14 cents or 7.95 percent to \$1.90 with 223,794 shares traded.

Living Cell, Patrys and Starpharma climbed five percent or more; Phosphagenics was up 4.2 percent; Bionomics was up 3.3 percent; Sunshine Heart and Tissue Therapies rose more than two percent; with Heartware and Nanosonics up more than one percent.

Cellmid led the falls, down 0.2 cents or 8.3 percent to 2.2 cents with 260,000 shares traded, followed by Virax down 8.2 percent to 6.7 cents with 102,900 shares traded.

Optiscan lost 7.3 percent; Antisense and Genetic Technologies fell more than five percent; Novogen was down 3.7 percent; Uscom and Viralytics shed more than two percent; with Cellestis, Clinuvel, Pharmaxis and Resmed down more than one percent.

[BIOTECH DAILY EDITORIAL: DISCLOSURE](#)

Last night's edition reported on Athlomics a private company developing a test for sepsis, noting that Commercialisation Australia awarded Athlomics \$250,000 for its Septicyte product and that Athlomics director Dr Laurie Hammond was the chairman of Commercialisation Australia.

Biotech Daily has been assured that the Department of Innovation and Commercialisation Australia ensured propriety at every step and Dr Hammond was not involved in the grant process for Athlomics, but the July 14, 2010 media release from Innovation Minister Senator Kim Carr did not say so.

The Department said the Minister did not need to be informed, implying that was why the disclaimer had not been reported.

Had the media release stated the disclosure in the form "Commercialisation Australia chairman Dr Laurie Hammond is a director of Athlomics and took no part in the grant process", the matter would have been transparent, open and left there.

The fact that it was not disclosed raises questions on what else has not been disclosed in relation to these grants. Biotech Daily requested a list of personnel who have disqualified themselves from the grant process and the companies to which they are related, but the Department refused saying: "There is no need for a public declaration. We are satisfied that the conflict of interest processes that we have in place are rigorous ... and they ensure that all assessments are undertaken fairly."

This is not the first time potential conflicts of interest have come to light. In 2007, the chairman of the Cooperative Research Program Committee, Dr Peter Jonson, was the chairman and a shareholder of Bionomics, when \$36.7 million was granted to establish the CRC for Cancer Therapeutics, of which Bionomics was one of three partners.

Karmelsonix director Dr Henry Pinski was on Victorian Government boards when a separate board awarded his company the first Victoria Israel Technology Fund grant. These matters should be declared.

And there are several sub-stories to the lack of transparency.

Biotechnology is a relatively small, close-knit sector, so it is inevitable that people will know each other. In many ways it is a very positive attribute, but where there are direct relationships, transparency and disclosure remove any hint of impropriety.

The act of disclosure itself can be influential and Biotech Daily's shareholdings are boasted as much as they are disclosed, moreso when they have improved in value.

Should an influential person disqualify themselves from a grant hearing, their colleagues could be forgiven for thinking: "We have two equal applications, but that person is a major shareholder in one, so it is probably a better company." This problem is insurmountable without independent assessors, but that takes us back to the close-knit community.

When a sector is competitively bidding for very limited taxpayer funds, a grant must be totally transparent, as one company's success is a failure for others.

Finally, the chooks come home to roost for the Department of Innovation ignoring the Biotechnology and Related Industries Group submission on Commercialisation Australia: <http://www.biotechdaily.com.au/media/editorials/BRIL%20Group%20CCI%20Proposal.pdf>.

The proposal said the funding body should be at arms length from Government, which in this case would mean that neither the Department nor the Government could be blamed for the actions of a quasi-autonomous non-government organization. Instead, the Department and Government chose to retain Commercialisation Australia under its roof. The Department and the Minister need to take responsibility for the lack of transparency in the spending of very scarce taxpayer funds for innovative industries.

David Langsam, Editor.
Marc Sinatra, Analyst

MESOBLAST

The Australian Therapeutic Goods Administration has approved a commercial licence for Mesoblast to manufacture and supply its mesenchymal precursor cell products.

Mesoblast chief executive Prof Silviu Itescu said it was believed to be the first such approval in the world.

Mesoblast said it would be able to commercially provide autologous or patients' own mesenchymal precursor cells to doctors and hospitals in Australia for use in the repair and regeneration of their damaged tissues.

Mesoblast said the cells would be manufactured by Cell Therapies Pty Ltd.

Mesoblast said initially it would target major bone repair markets, including long bone fractures after trauma, stress fractures following sporting injury and vertebral fractures due to osteoporosis.

Prof Itescu said that gaining a licence from the TGA "to manufacture our adult stem cell products for supply to Australian patients is a major validating step in Mesoblast's history". "It underscores the robustness of our manufacturing process and the excellent safety profile of our products in patients," Prof Itescu said.

"To our knowledge, this is the first culture-expanded adult stem cell product that has received manufacturing approval anywhere in the world," Prof Itescu said.

Prof Itescu said that Australian TGA approval meant early revenue generation for Mesoblast, faster product adoption and branding and accrual of clinical outcome data for use by the company in subsequent local and international filings for product registrations. Prof Itescu said the manufacturing licence would position Australia "as a global leader in the use of regulated stem cell therapies".

Mesoblast climbed 14 cents or 7.95 percent to \$1.90.

PHARMAXIS

Pharmaxis quarterly report to shareholders says there were many positives from the phase III clinical trial of Bronchitol in cystic fibrosis, which narrowly missed its endpoint.

Pharmaxis acting chief executive officer Gary Phillips said Bronchitol "yet again demonstrated that patients taking it can expect an early improvement in lung function that is sustained over six months".

Mr Phillips said the control group had a bigger improvement than in the earlier study (CF301) but there was more variability in the data which lead to the trial missing its primary endpoint of the difference in volume between active and controls when measured as forced expiratory volume over one second (FEV1) (BD: Jun 23, 2010).

Mr Phillips said the European Union submission was "on-track and is supported by CF302, which confirms that Bronchitol has an acceptable safety profile".

He said preparation of the US Food and Drug Administration submission was ongoing "and we remain confident that the overall clinical program will support a positive outcome".

He said about one percent of all diagnosed cystic fibrosis patients in the world had been trialed on Bronchitol and Pharmaxis had "a compelling body of evidence to support our US submission, which we look forward to discussing with the FDA later this year".

The company did not specify when the meeting was expected.

Mr Phillips said comprehensive analysis of the trial data had begun and would be presented at the North American cystic fibrosis conference in Baltimore, Maryland, October 21-23, 2010.

Mr Phillips said the other measures in the trial showed significant improvement in patients lung function.

Pharmaxis fell three cents or 1.4 percent to \$2.11.

COCHLEAR

The US based Capital Group Companies has reduced its substantial shareholding in Cochlear from 6,193,350 shares (10.95%) to 5,618,543 shares (9.94%).

Capital Group had been increasing its holding since November 3, 2008 when it had 8.80 percent of the company and last increased its holding in September 2009.

Capital Group said it reduced its substantial shareholding from 12.00 percent to 10.95 percent on July 12 (BD: Jul 13, 2010).

Capital Group said it did not own shares in Cochlear but held them on account for Capital Research and Management Company.

The 574,807 shares were sold at an average price of \$72.73.

Cochlear climbed 18 cents or 0.24 percent to \$74.43.

NEUREN PHARMACEUTICALS

The New York-based Springtree Special Opportunities Funds told the ASX through Neuren that it held 5.48 percent of the New Zealand-based, ASX-listed company.

While Springtree disclosed that it held 5.48 percent of Neuren's total shares on issue of 389,636,587 or about 21,352,084 shares, the company refused to disclose its precise share holding.

Springtree said in its notice to the ASX that its legal counsel had advised that it was "not required to lodge a substantial shareholder notice with the ASX, due to Neuren being an entity established outside of Australia".

Springtree said that it was disclosing its percentage holding "notwithstanding the fact that we have no obligation to lodge a substantial shareholder notice with the ASX or advise you of our holding".

An Australian Securities and Investments Commission spokeswoman directed Biotech Daily to Section 671B of the Corporations Act 2001 which sets strict regulation on submitting substantial shareholder notices.

The Act contained no obvious exemption for ASX-listed companies based in third countries.

An ASIC spokeswoman told Biotech Daily that Section 671B of the Corporations Act applied to all ASX-listed companies regardless of country of domicile and that the substantial shareholder notices must be in the approved form including the number of shares and percentage.

Neuren was unchanged at 2.1 cents.

* Biotech Daily editor David Langsam holds Neuren shares.

EASTLAND MEDICAL SYSTEMS

Eastland has appointment Stephen Carter as a consultant.

Eastland said Mr Carter had "an extensive pharmaceutical background" and had been a non-executive chairman, managing director and chief executive officer of ASX-listed companies.

The company said Mr Carter would strengthen the company's public relations and communications with the capital markets and assist our technical director Calvin Ross in screening new projects.

Eastland said Mr Carter had experience in liaising with capital markets as well as managing administrative, technical, clinical and regulatory programs.

Eastland fell 0.2 cents or 4.65 percent to 4.1 cents.

ANTISENSE

Antisense says Kate Plumridge has resignation as joint company secretary but will continue to work with the company until August 31, 2010.

Antisense said Ms Plumridge joined Phillip Hains, both of the CFO Solution, in the role of joint company secretary in October 2007.

Mr Hains continues as Antisense's company secretary.

Antisense fell 0.1 cents or 5.3 percent to 1.8 cents.