



Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 1.3 percent on Wednesday May 21, 2008 with the All Ordinaries down 78.5 points to 5,916.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, three traded unchanged and five were untraded.

Antisense was best, up 0.8 cents or 10.96 percent to 8.1 cents on moderate volumes, followed by Living Cell up 2.5 cents or 8.77 percent to 31 cents and Tissue Therapies up eight percent to 13.5 cents. Mesoblast was up 5.48 percent; Agenix climbed 4.88 percent; Phosphagenics was up 3.85 percent; Clinuvel, CSL and Peplin rose more than two percent; with Universal Biosensors up 1.15 percent.

Genetic Technologies led the falls down one cent or 9.09 percent to 10 cents on small volumes, followed by Starpharma down 7.14 percent to 32.5 cents. Bionomics and Portland lost more than six percent; Arana, Chemgenex and Neuren fell more than four percent; Acrux, Benitec, Cellestis and Optiscan were down more than three percent; Alchemia, Novogen, Pharmaxis, Phylogica, Polartechnics and Prana shed more than two percent; with Avexa, Cytopia, Sirtex and Ventracor down more than one percent.

EDITORIAL: TAXATION, INVESTMENT AND BIOTECHNOLOGY

Biotech Daily has called for superannuation funds to be allowed to invest in the sector along with investment tax relief.

In a submission to the Review of the National Innovation System, Biotech Daily said the key issue facing the biotechnology and medical technology sector was long-term funding for long-term research and development.

While the Commercial Ready and other grants serve a purpose, they are not the prime methods of funding the commercialization of Australia's disproportionately high quantity of innovative bio and medical technologies.

Both the ASX-listed and private companies need significant levels of funding to take a university or institute-developed compound or device through clinical trials to the goal of Australian Therapeutic Goods Administration, European Medicines Agency and US Food and Drug Administration registration.

The submission says there needs to be a mechanism giving investors an incentive to fund innovative companies and called for changes to superannuation investment as well as tax relief measures for investors.

Superannuation

The Government-approved industrial superannuation funds must be allowed to copy the Californian model and invest up to 1.0% of funds in specified* biotechnology companies.

150% Tax Deductible Investments

Institutional and retail investors should be given an incentive to make long term investments in specified* biotechnology companies.

One model is a renovated version of the Whitlam era 150% tax deductibility for investment in the film industry. The money came in and an industry was created. The problem was that along with good (non-profitable) documentaries, some poor films were made and most of the profits were apparently made by distributors and a select few in the industry. A mechanism needs to be created to return distribution and end-of-pipeline profits. For biotechnology, the tax deductibility could be allowed for specified* companies with a levy on pharmaceutical sales and distribution profits hypothecated to a biotechnology fund.

Capital Gains Tax Discount

Individuals and superannuation funds are entitled to a 50% capital gains tax discount if they hold shares in a company for more than 12 months. This should be extended to companies investing in specified* biotechs, rising to a 75% discount for holding the shares for more than two years and 100% for holding the shares for more than three years.

* Specified companies

The types of companies that require assistance are only those with early stage innovative research and development. The assistance must be means tested. Companies making significant profits should not be the recipients of Government largesse.

To qualify as a specified company:

- i) the entity must be involved in an Australian developed technology, not one bought in from another country (possibly exempting New Zealand). The source technology must be Australian.
- ii) the entity must be conducting research and development in Australia and not farming out the work to an offshore contract research organization. The work can be sub-contracted to an Australian (or New Zealand) contract research organization.
- iii) the entity must be an Australian-based company, not merely ASX-listed and operating from an office off-shore.

David Langsam, editor

Marc Sinatra, analyst

[STARPHARMA](#)

Starpharma chief executive officer Dr Jackie Fairley says her company's dendrimer nanotechnologies are unrelated to asbestos-like carbon nanotubes.

An article published in the journal Nature Nanotechnology has raised concerns about the asbestos-like cancer effects of carbon nanotubes.

The chief science advisor to the Project on Emerging Nanotechnologies and a co-author on the paper Andrew Maynard said that "even though scientists had been raising concerns about the safety of long, thin carbon nanotubes for over a decade, none of the research needs in the current US federal nanotechnology environment, health and safety risk research strategy address this question".

Dr Fairley said that long carbon nanotubes had characteristics that are unique compared with any other material, but have a needle-like shape similar to asbestos, lead to an inflammatory response and the formation of lesions.

She said these effects were seen when the mesothelial lining of the chest of mice were exposed, via the abdominal cavity, to carbon nanotubes with a length surpassing approximately 20µm (20,000nm). These effects were not seen when carbon nanotubes samples with no or low detectable levels of such long fibres were tested.

These important findings support the postulated paradigm that a hazardous fibre is one that is thinner than 3µm (3,000nm), longer than 20µm (20,000nm) and biopersistent in the lungs.

Dr Fairley said adverse effects were seen when the number of fibres reach a sufficient level to cause a chronic inflammatory response, genotoxicity, fibrosis and cancer. The study did not assess whether the long carbon nanotubes were biopersistent, which is another critical factor when considering the implications for human exposure. The study also did not show that the mice developed mesothelioma.

Dr Fairley said dendrimers synthesized for pharmaceutical and industrial applications by Starpharma were "very different in terms of dimension (diameter and length) and composition" to both long and short carbon nanotubes.

She said the typical maximum dimensions of a dendrimer are in the range of approximately 10nm and the molecules were not long or fibre-like.

Instead, they are roughly spherical.

Key properties of carbon nanotubes are their inertness and strength.

In contrast, dendrimers are typically synthesized from naturally occurring building blocks, such as amino acids and can be designed to have a controlled rate of metabolism in the human body.

Dr Fairley said Starpharma's dendrimers showed they were metabolized to their subunits (the amino acid lysine).

"Therefore, as opposed to [carbon nanotubes], dendrimers are not fibre-like, nor biopersistent, and do not fit the accepted paradigm that applies to hazardous fibres," Dr Fairley said.

"Starpharma has undertaken an extensive toxicology program to support the development of its pharmaceutical products," she said.

"In particular, studies on SPL7013 and SPL7013 Gel (Vivagel), have shown no adverse effects in a range of genotoxicology studies which are designed to detect compounds that could potentially cause cancer," she said.

"Furthermore, Vivagel is currently being tested in two multi-year carcinogenicity studies which are in the mid to late stages of conduct and with no deleterious effects of this dendrimer-based product observed to date," Dr Fairley said.

Starpharma fell 2.5 cents or 7.14 percent to 32.5 cents.

IMPEDIMED

Impedimed says Northern Ireland guidelines support the use of its bioimpedance technology.

Impedimed said the Clinical Resource Efficiency Support Team published Guidelines for the Assessment and Monitoring of Lymphoedema which rated bioimpedance as the only technology high in sensitivity and specificity.

Impedimed has the only US Food and Drug Administration cleared device for the clinical assessment of lymphoedema in the arm.

Impedimed said that in clinical trials its technology detected lymphoedema in breast cancer survivors one to 10 months earlier than clinically observable symptoms.

Impedimed chief executive officer Greg Brown said the Irish Guidelines were "a significant step forward" in the recognition of the bioimpedance technology.

He said it was "particularly pleasing to note the Guidelines recommend the use of a baseline measurement on patients prior to surgery or radiotherapy".

"This surveillance method of diagnosis and treatment mirrors recommendations contained in the recently published ground breaking study by the US National Institutes of Health published online in ... Cancer, the official journal of the American Cancer Society."

"According to data from the NIH study the preoperative assessment of breast cancer patients for sub-clinical lymphoedema enables the early detection and successful treatment of the debilitating condition," Mr Brown said.

He said the Guidelines noted that, although bioimpedance was not generally available in Northern Ireland, it was a promising, effective and efficient way of assessing and monitoring lymphoedema and should be considered for use in the longer term.

The company said that its devices were being used in many of the centres involved in establishing the Guidelines.

Impedimed was untraded at 75 cents.

CYCLOPHARM

Cyclopharm has received regulatory approval for the sale of Technegas products in Brazil. The company said it was "a significant achievement" and coincided with its first sales of Technegas products in Mexico.

Cyclopharm said Brazil was that largest market for nuclear medicine in Latin America and there were about 350 nuclear medical centres in Brazil, which also has the highest medical rebate for lung scanning in Latin America.

Cyclopharm was up 1.5 cents or 8.57 percent to 19 cents.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical has received notification that it has been granted a US patent for its hip cup design, for use in hip replacement surgery.

Advanced Surgical said the patent was in addition to a patent granted in 2000 and also relating to the features of the innovative hip cup.

The Advanced Surgical design has flexibility in placement and orientation of the hip cup into the patient's bone; peripheral loading of the bone encouraging excellent bone response and eliminating unfavorable apical loading; and the polyethylene liner is separated from the back of the implanted cup by a metal shell to eliminate polyethylene wear particles accessing this interface to the bone, a major source of hip cup failure.

Advanced Surgical said these features were "a significant advance in hip arthroplasty".

Advanced Surgical climbed five cents or 10 percent to 55 cents.

NORWOOD ABBEY

Norwood Abbey says the US Patent office has granted an additional patent to the Massachusetts Institute of Technology related to Norwood Abbey's research.

The company said it had a licence over the patent entitled 'Microneedle Transdermal Transport Device' and all intellectual property flowing from its sponsored research at MIT. Norwood Abbey said the microneedle patent comprised 50 claims and covered a horizontal needle concept for delivering drugs.

"Control of depth is achieved through the skin being drawn up into holes or ports with a prescribed depth, after which the needles are inserted horizontally and hence drugs are delivered horizontally," Norwood Abbey said.

Norwood was up 0.6 cents or 31.58 percent to 2.5 cents with 14.4 million shares traded.

ARANA

Arana's net profit after tax for the six months to March 31, 2008 was \$1.6 million on revenue up 10.5 percent to \$19.7 million.

The revenue came primarily from royalties of \$8.6 million, sales and licencing income of \$4.6 million along with grant revenues and the net gain on the Domantis sale.

Arana said the profit was in line with the previous corresponding period's \$137.7 million which included the \$136.1 million sale of Domantis.

Net tangible asset backing was 78.8 cents a share, earnings per share was 0.49 cents.

A dividend will not be paid. Cash was \$181.7 million up from \$169.0 million in 2007.

Arana fell 4.5 cents or 4.33 percent to 99.5 cents.

PRANA

Prana has raised \$7 million in a placement to existing investors at 40 cents a share.

Prana chief executive officer Geoffrey Kempler said the funds would boost research and development of the pipeline for treatments for Alzheimer's and other neurodegenerative diseases, such as Parkinson's and Huntington's disease.

Prana fell one cent or 2.44 percent to 40 cents.

WOMEN IN SCIENCE AWARDS

Applications are open for the 2008 L'Oréal Australia For Women in Science Fellowships.

A media release said the three \$20,000 fellowships recognized scientific excellence by early-career women in the life sciences, material sciences, physical sciences, mathematics or engineering, who have completed their doctorate of philosophy or equivalent in the last five years.

The fellowships are supported by the Australian National Commission for UNESCO and endorsed by the Australian Academy of Science.

Last year's fellowships were awarded to the Garvan Institute's Dr Jenny Gunton for her study exploring the link between vitamin D and diabetes; the Commonwealth Scientific and Industrial Research Organisation's Dr Ilana Feain for her study of black holes and their role in the birth and death of stars and galaxies; Monash University's Dr Catriona Bradshaw for her study of the transmission of a common genital infection, bacterial vaginosis; and Macquarie University's Dr Sarah Pryke for her study of the evolution and conservation of Gouldian finches.

The closing date is June 20, 2008.

More information is at: <http://www.scienceinpublic.com/loreal>

HEARTWARE

Heartware has requested a trading halt pending an announcement regarding a capital raising.

Trading will resume on May 23, 2008 or on an earlier announcement.

Heartware last traded at 50.5 cents.

GENERA

Genera Biosystems says its \$5 million initial public offer of 10,000,000 shares at five cents a share has closed oversubscribed with all ASX requirements satisfied.

Genera extended the IPO to reach the 400 investor minimum required for an ASX listing. The company hopes to commercialize molecular diagnostics technologies for women's health, including DNA detection and genotyping systems, a sensitive, versatile and real-time optical detection system with point-of-testing potential and proprietary interpretive software (see Biotech Daily April 30, 2008).

Genera's prospectus said the technologies originated from the Walter and Eliza Hall Institute, the Australian Genome Research Facility and the University of Melbourne. Genera will begin trading on the ASX in the first week of June 2008, under the ticker symbol GBI.

The market capitalization of Genera Biosystems will be about \$25 million on listing.

Chairman Fernando Careri said the oversubscribed IPO was a testament to the strength of Genera's business case.

"The next two years will be an exciting time for the company, as we progress towards full commercialization of our Paptyp HPV diagnostic, and other tests," Mr Careri said.

Paptyp is used to identify human papillomavirus, responsible for most cases of cervical cancer in cervical smear specimens. The company also has a test for other sexually transmitted diseases at an advanced stage of pre-clinical development.

The IPO was managed by Melbourne's Domain Capital.

METABOLIC

Metabolic has appointed Franklyn Brazil and Paul Lappin as non-executive directors, effective immediately.

Mr Brazil bought Circadian's 12 percent holding in the company through Iain Kirkwood's Edward St Consulting (see Biotech Daily; May 14, 2008).

Mr Kirkwood was appointed to the Metabolic board on April 30, 2008.

Mr Brazil was the founding investor and a former director of Wotif.com, an online hotel accommodation provider.

Mr Lappin is a chartered accountant with experience in finance and mergers and acquisitions.

Mr Lappin has worked for the commercial arm of Commonwealth Scientific and Industrial Research Organisation on strategic and business planning assignments and is the executive chairman of Peter Rowland Catering.

Metabolic climbed 0.3 cents or 7.5 percent to 4.3 cents.