



Biotech Daily

Friday May 25, 2012

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: GENETIC TECHNO UP 48%, ELLEX DOWN 11%**
- * **TGA APPROVES ACRUX, ELI LILLY AXIRON**
- * **GSK OPENS COMBINATION MELANOMA PHASE III TRIAL**
- * **GENETIC TECHNOLOGIES UP 98% FOR THE WEEK**
- * **BIO-MELBOURNE HIRAOKI KITANO DRUG ENGINEERING BREAKFAST**
- * **AUSTRALIAN ETHICAL INCREASES TO 7% IN NEUREN**
- * **IMMURON APPOINTS DR ROGER ASTON, CEO JOE BAINI DIRECTORS**
- * **IAIN ROSS REPLACES TISSUE THERAPIES DIRECTOR GREG BAYNTON**
- * **SWAPNA KESKAR REPLACES NUSEP CO SEC TOM ROWE**

MARKET REPORT

The Australian stock market fell 0.66 percent on Friday May 25, 2012 with the S&P ASX 200 down 26.6 points to 4,029.2 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 10 fell, 13 traded unchanged and four were untraded.

Genetic Technologies was the best, again following the Nasdaq (see below), climbing as much as 7.5 cents or 65.2 percent to 19 cents, closing up 5.5 cents or 47.8 percent to 17 cents with 14.7 million shares traded and up 97.7 percent for the week.

Viralytics climbed 15 percent; Clinuvel and Neuren were up more than eight percent; Compumedics was up 6.7 percent; Reva was up 4.5 percent; Acrux, Optiscan and Psivida rose more than two percent; Sirtex and Starpharma were up more than one percent; with Cochlear, Heartware and Mesoblast up by less than one percent.

Ellex led the falls, down two cents or 10.5 percent to 17 cents with 3,860 shares traded.

Impedimed and Universal Biosensors lost more than seven percent; Alchemia was down 6.4 percent; Prima was down 3.3 percent; Prana shed 2.9 percent; Anteo, Biota, CSL and Pharmaxis were down more than one percent; with QRX down 0.55 percent.

[ACRUX](#)

Acrux says the Australian Therapeutic Goods Administration has approved the marketing of its Axiron testosterone replacement treatment.

Acrux said that partner Eli Lilly received the approval to market Axiron in Australia from the TGA to sell Axiron as an androgen replacement therapy for confirmed testosterone deficiency in males.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily that he was pleased that Axiron had received first time approval and that the Pharmaceutical Benefits Advisory Committee had approved the listing of Axiron on the Pharmaceutical Benefits Scheme. Despite US Food and Drug Administration approval for its Ellavie estradiol spray for the treatment of menopause, the TGA did not grant approval, requiring a further trial, which Acrux declined (BD: Nov 12, 2009).

More recently, Pharmaxis made several applications to the Pharmaceutical Benefits Advisory Committee before being recommended for listing on the Pharmaceutical Benefits Scheme (BD: Mar 14, 2012).

Acrux said that Axiron was launched by Lilly in the US in 2011 and had been approved in Canada, with regulatory approval in select European countries expected during 2012.

The company said it expected expansion into Asian and South American markets.

Acrux chairman Ross Dobinson said the first product developed by Acrux to be made available to Australians was a milestone.

"The technology behind Axiron originated at Monash University and its development by Acrux over a decade has been supported by our shareholders as well as Federal and State governments through competitive grants and tax concessions," Mr Dobinson said.

"This support has been critical and the benefits for all Australian stakeholders are now being realized as Axiron is commercialized around the world," Mr Dobinson said.

Acrux said it expected expects to begin earning royalties on net sales of Axiron in Australia during the 2012-'13 financial year.

Acrux was up 10 cents or 2.4 percent to \$4.26 with two million shares traded.

[GLAXOSMITHKLINE](#)

Glaxosmithkline is recruiting patients for a phase III trial comparing dabrafenib and trametinib to dabrafenib and placebo as first-line therapy for V600E/K mutation melanoma. Glaxosmithkline said the randomized, double-blind study would compare the combination of the BRAF inhibitor (BRAF-i), dabrafenib and the MEK inhibitor (MEK-i), trametinib to dabrafenib and placebo as first-line therapy in subjects with BRAF V600E/K mutation positive metastatic cutaneous melanoma.

The company said that Westmead Hospital melanoma specialist and the study's key investigator Prof Richard Kefford said the study would be crucial to assess the clinical benefits of combining new agents in the treatment of metastatic melanoma.

"We are making some remarkable progress now in identifying promising compounds and testing combinations of them in well constructed trials," Prof Kefford said.

In 2010, Glaxosmithkline began a phase III trial of its BRAF-i for melanoma GSK2118436 and said it was also conducting trials with investigational agents targeting a range of pathway proteins, involved in melanoma cell growth (BD: Nov 16, 2010).

The company said at that time that one study would explore whether, when used in combination, its MEK-i and BRAF-i could provide better patient outcomes and said it was conducting a phase I, open-label, dose-escalation study of the safety, pharmacokinetics, pharmacodynamics and clinical activity of the BRAF-i GSK2118436 in combination with the MEK-i GSK1120212 in subjects with BRAF-mutant metastatic melanoma.

GENETIC TECHNOLOGIES

Genetic Technologies climbed a further \$US2.22 or 62.7 percent to \$US5.76 with 5.8 million shares traded on the Nasdaq last night a 139 percent rise in three days. Earlier this week on the Nasdaq, Genetic Technologies climbed \$US1.58 or 65.6 percent to \$US3.99 followed by an 11.5 percent easing (BD: May 23, 24, 2012).

As reported on May 23, the price movement appears related to an announcement of increased sales of the Brevagen breast cancer test, which did not provide specific numbers, as well as an update on coverage and reimbursement in the US.

Lodge Partners analyst Marc Sinatra told Biotech Daily "there seems to be a swing back of market sentiment in the US for personalized medicine companies".

"This has been most evident in the Rosetta Genomics stock price, which has gone up 10-fold from \$US1.67 on May 15 to \$US16.29 overnight," Mr Sinatra said.

Lodge Partners has a corporate relationship with Genetic Technologies.

On the ASX today, Genetic Technologies climbed as much as 65.2 percent to 19 cents, closing up 5.5 cents or 47.8 percent to 17 cents with 14.7 million shares traded.

BIO-MELBOURNE NETWORK

Tokyo's Systems Biology Institute president Prof Hiraoki Kitano will discuss the role of engineering in drug discovery at the Bio-Melbourne Network's June 5 bio-breakfast.

The Bio-Melbourne Network said that Prof Kitano was also the president of Sony Computer Science Laboratories and would describe how in the next decade, lab-on-a-chip drug development technology could replace traditional assays and that microscale technologies, imaging, computational and systems biology, robotics and biomaterials would be used as standard.

Bio-Melbourne chief executive officer Michelle Gallaher said "we are already seeing the positive impact of cellular and molecular modeling in reducing risk, predicting outcomes and providing significantly faster processing and greater diversity and scope for research".

"In future we may find that modeling has created opportunities for investigation that would be otherwise impossible using traditional wet lab processes and indeed supersedes this technology," Ms Gallaher said.

The Network said that Prof Kitano was a professor at the Okinawa Institute of Science and Technology, director of cancer systems biology at the Cancer Institute of Japan Foundation for Cancer Research and a visiting professor at Monash University.

The Network said that Prof Kitano was an expert in bioinformatics, systems biology and artificial intelligence and a leading figure in the emerging field of gene network modeling.

The June 5, 2012 Bio-Breakfast will be held at the Australian Centre of the Moving Image, Federation Square, Melbourne. Registration is from 7:15am, with the presentation at 8am.

For more information go to: <http://www.biomelbourne.org/events/view/235>.

NEUREN PHARMACEUTICALS

Australian Ethical Smaller Companies Trust has increased its substantial shareholding in Neuren from 68,716,436 shares (5.95%) to 80,835,436 shares (6.99%)

In December 2011, Australian Ethical sold 13,673,352 shares for \$433,697 or an average price of 3.17 cents a share, a 143.8 percent profit before tax having acquired 96,153,840 shares for \$1,250,000 or 1.3 cents a share (BD: Aug 16, 17, Dec 12, 2011).

Today, Australian Ethical said the most recent acquisition was 3,000,000 shares for \$72,000 or 2.4 cents a share.

Neuren was up 0.2 cents or 8.7 percent to 2.5 cents with 10.1 million shares traded.

IMMURON

Immuron has appointed Dr Roger Aston as non-executive director and chief executive officer Joe Bains as an executive director, effective immediately.

Immuron chairman Prof Colin Chapman said that Dr Aston was "one of the most senior and best respected individuals in the biopharmaceutical world, with significant experience in manufacturing clinical development and commercialization".

The company said that Dr Aston was recently appointed as a director of IDT and prior to that was the founding chief executive officer of Mayne Pharma after leading Halcyon's acquisition of Mayne in 2009.

Immuron said that Dr Aston had experience with US Food and Drug Administration and European product registration, clinical trials, global licencing agreements, fundraising through private placements and preparation of prospectuses and had a strong network in the pharmaceutical, banking and stock broking sectors.

The company said Dr Aston was previously a chairman or director of Clinuvel, Halcyon Mayne Pharma and Ascent Pharma.

Immuron fell 0.1 cents or five percent to 1.9 cents.

TISSUE THERAPIES

Tissue Therapies says Iain Ross has been appointed as a director replacing Greg Baynton.

Tissue Therapies said that Mr Ross was an experienced biotechnology company chairman and director with international experience, particularly in the UK, Europe and Australia and was based in the UK.

Tissue Therapies said that Mr Baynton has decided to resign as a director to pursue other commercial interests and his resignation would take effect following the next board meeting on June 12, 2012.

Tissue Therapies was unchanged at 48.5 cents.

NUSEP

Nusep says Swapna Keskar has replaced Tom Rowe as company secretary, effective immediately.

Nusep said that Ms Keskar was an experienced company secretary and with Mr Rowe works for Company Matters Pty Ltd so the appointment is a continuation of the existing engagement with Company Matters.

Nusep was untraded at 3.5 cents.