# Biotech Daily

Tuesday June 3, 2008

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECHS DOWN: AGENIX UP 11%, ANTISENSE DOWN 18%**

*** CANCER STUDY 'CONFIRMS BENEFIT' OF SIRTEX SIR-SPHERES**

*** CHEMGENEX PUBLISHES FURTHER PHASE II/III TRIAL DATA**

*** VIRAX CO-X-GENE LICENCEE POST 'SUCCESSFUL' PHASE IIB TRIAL**

*** ARANA, GREENOVATION COMBINE ON CANCER ANTIBODIES**

*** BIOSIGNAL PLACEMENT RAISES $400k**

*** LIVING CELL 1st NZ COMPANY TO TRADE ON US OTCQX**

*** GUN, LEO KHOURI INCREASE TO 14% OF BIOPROSPECT**

*** DECKCHAIR TAKES 6% OF INCITIVE**

*** QRX BEGINS ADR PROGRAM**

*** PROF IAN FRAZER JOINS AVANTOGEN'S HAWAII SCIENCE BOARD**

## MARKET REPORT

The Australian stock market fell 1.4 percent on Tuesday June 3, 2008 with the All Ordinaries down 78.2 points to 5,703.0 points. Nine of the Biotech Daily Top 40 stocks were up, 22 fell, six were unchanged and three were untraded.

Agenix was best, up 0.8 cents or 11.43 percent to 7.8 cents on modest volumes, followed by Phylogica up 11.11 percent to nine cents.

Mesoblast climbed 6.1 percent; Clinuvel was up 5.56 percent; Bionomics rose 4.55 percent on a report that its lead drug was in a publication's Top Five; Chemgenex and Neuren climbed more than three percent; Arana rose 2.46 percent; with CSL and Circadian up more than one percent.

Antisense led the falls, down 1.2 cents or 17.91 percent to 5.5 cents, followed by Portland down 14.63 percent to 3.5 cents with Optiscan and Psivida down more than 10 percent.

Alchemia lost 7.69 percent; Polartechnics was down 6.67 percent; Biota, Living Cell, Novogen, Pharmaxis and Sirtex fell more than five percent; Cellestis, Genetic technologies and Phosphagenics fell more than four percent; Avexa, Cochlear and Proteome were down more than three percent; Acrux shed two percent; with Benitec, Peplin, Progen, Universal Biosensors and Ventracor down more than one percent.

SIRTEX

Sirtex says a multicentre trial has shown its SIR-Spheres provide “substantial clinical benefit” for patients with colorectal cancer that has spread to the liver and have failed available chemotherapy options.

Sirtex said the independent, prospective, multicentre phase II study was conducted by the Italian Society of Locoregional Therapies In Oncology and reported at the American Society of Clinical Oncology conference held in Chicago, May 30-June 3, 2008.

Sirtex said the study was the first prospective clinical trial of SIR-Spheres microspheres in the salvage therapy of patients with colorectal cancer liver metastases who have been heavily pre-treated with chemotherapy.

The company said the results showed “a median overall survival of 13 months, with an overall response rate of 24 percent and stable disease reported in a further 24 percent of patients.

The tumors shrank sufficiently to permit the surgeons to plan potentially curative surgery in two patients.

Patients that responded to SIR-Spheres microspheres had a significantly longer median survival compared to non-responders (16 months compared to eight months; p = 0.0006), with 40 percent of the responders remaining alive at two years compared to none of the non-responders.

Sirtex said treatment with SIR-Spheres microspheres was well tolerated, with side effects in the first 30-days post-treatment consisting mostly of fever in 16 percent of patients in the first 48 hours and 22 percent after 48 hours.

Sirtex chief executive officer Gilman Wong said the study results confirmed the results of retrospective studies on SIR-Spheres microspheres in routine clinical practice and compared favorably with the results of chemotherapy alone.

“These results clearly demonstrate that SIR-Spheres microspheres should, at a minimum, be used for patients with colorectal cancer liver metastases who have failed chemotherapy,” Mr Wong said.

“However, the investigators also noted the potential for SIR-Spheres microspheres to be combined with chemotherapy in order to further increase the effectiveness of treatment at earlier stages of the disease,” Mr Wong said.

Sirtex said its selective internal radiation therapy using SIR-Spheres microspheres was a treatment for inoperable liver tumors that delivered high doses of radiation directly to the site of the tumors.

The company said that in a minimally invasive treatment, millions of radioactive SIR-Spheres microspheres were infused via a catheter into the liver where they selectively targeted liver tumors with a dose of radiation up to 40 times higher than can be safely delivered by convention radiotherapy, while at the same time sparing healthy tissue.

Sirtex said clinical trails confirmed that patients with liver cancer treated with SIR-Spheres microspheres had higher response rates and longer time to progression of the disease as well as survival compared with other forms of treatment.

This leads to an increased life expectancy, greater periods with tumor activity and improved quality of life compared to chemotherapy alone, Sirtex said.

Selective internal radiation therapy is used in Australia, New Zealand, the US, Europe, Hong Kong, Israel, Malaysia, Singapore, Taiwan, Thailand and Turkey with more than 7,500 patients treated to date.

Sirtex said that secondary liver cancer was the ultimate cause of death in one in three cancer sufferers and liver tumors were typically inoperable in 90 percent of cases and are usually incurable with chemotherapy.

Sirtex fell 22 cents or 5.66 percent to $3.67.

## CHEMGENEX

Chemgenex says 60 percent of Gleevec-resistant chronic myeloid leukemia patients treated with omacetaxine had “complete disappearance of the T315I mutation clone”.

Chemgenex is developing omacetaxine mepesuccinate (formerly Ceflatonin) for chronic myeloid leukemia patients with the T315I mutation and for whom there are currently no effective drug treatments.

Chemgenex senior vice-president and chief medical officer Dr Adam Craig presented the phase II/III data on omacetaxine mepesuccinate (formerly Ceflatonin) on behalf of a team including investigators from Chemgenex and US and French research centers in a poster discussion session at the American Society of Clinical Oncology 44th annual meeting in Chicago.

The investigators reported that omacetaxine administered as a subcutaneous injection was generally well tolerated and demonstrated durable complete haematological and cytogenetic responses in patients who have failed to respond to the tyrosine kinase inhibitor imatinib mesylate (Gleevec) the current, standard front-line treatment.

Chemgenex’s multi-center, registration-directed clinical trial of omacetaxine is in imatinib-resistant chronic myeloid leukemia (CML) patients with the T315I mutation.

The company said the T315I mutation was the most common mutation that has emerged as a result of repeated use of imatinib and second-generation tyrosine kinase inhibitors such as dasatinib and nilotinib.

“The T315I mutation is the major therapeutic challenge in the management of CML and the introduction of a novel product such as omacetaxine which has a novel mode of action independent of the current treatments, may offer a solution to the current and growing unmet medical need in this patient group,” Dr Craig said.

To date 41 patients have been enrolled in the study and data was presented from 30 evaluable patients of which 17 were in chronic phase, eight were in accelerated phase and five in blast phase.

Chemgenex published data on 34 patients in April (see Biotech Daily; April 1, 2008). There was an overall haematologic response rate of 82 percent in chronic phase patients and 50 percent in accelerated phase patients and an overall cytogenetic response rate of 18 percent of chronic phase patients and 25 percent of accelerated phase patients.

Chemgenex reported a haematologic response for more than 15 months and cytogenetic response duration for longer than 10 months as well as a “complete disappearance of the T315I mutation clone in 60 percent of evaluable patients”.

The company said omacetaxine therapy continued to be well tolerated with manageable and reversible haematologic toxicity the most commonly reported side effect.

Chemgenex’s chief executive officer Dr Greg Collier said the updated data from the registration-directed trial “adds further to our growing confidence in the ability of omacetaxine to provide an effective therapy for the subset of CML patients who have unfortunately developed the T315I mutation and who have failed to respond to imatinib”.

“We are very encouraged by this preliminary clinical data, particularly the increased response durations in chronic and accelerated phase patients,” Dr Collier said.

He said the company was “on course” to file the non-clinical section of its rolling new drug application submission to the US Food and Drug Administration in mid-2008, to achieve our enrolment targets in 2008 and complete the submission in mid-2009.

In his update on Chemgenex (see Biotech Daily; May 5, 2008) Marc Sinatra reported that said there was “a substantial body of published evidence … much of it independent, to indicate that omacetaxine was efficacious in the treatment of CML and related diseases”.

Omacetaxine mepesuccinate is a semi-synthetic version of homoharringtonine.

Chemgenex was up three cents or 3.33 percent to 93 cents.

## VIRAX

Virax says France's Transgene SA has successful phase IIb data on TG4010 used with first line chemotherapy in patients with advanced non-small cell lung cancer.
Transgene has licenced Virax's Co-X-Gene technology for use in TG4010.
Virax said Transgene's trial met its primary endpoint for progression free survival at six months and that the response rate was "substantially higher for the combination of TG4010 with chemotherapy compared to chemotherapy alone".
Transgene chief executive officer Phillipe Archinard said the results "clearly warrant pursuing development into a phase III program and we will be seeking to establish a partnership in order to complete the last stages of clinical development and bring TG4010 to the market".
Virax's chief executive officer Larry Ward said the positive trial results were "further validation of both the Co-X-Gene technology and the significant commercial value of the Transgene licence".
"It is very exciting that both TG4010 and TG4001, products covered in the agreement with Transgene, should now soon enter phase III testing," Dr Ward said.
Virax said the Transgene licence allowed it to share fees and milestone payments in the event that Transgene sub-licences out either of the products and reaches development milestones.
Virax will also receive a royalty on net sales for the licenced products in North America.
Bryan Garnier and Co estimated peak annual sales of €750 million ($A1223 million) for TG4010 and €250 million ($A408 million) for TG4001 in a June 2005 report.
Virax has received milestone payments for TG4001 and licence fees totalling $2.2 million.
Virax jumped 1.4 cents or 45.16 percent to 4.5 cents.

## ARANA

Arana and Germany's Greenovation Biotech GmbH will combine their platforms to develop anti-cancer antibodies
Arana said the two companies have entered into a collaborative agreement to develop "next generation anti-cancer antibodies".
Arana and Greenovation will combine their respective technologies to develop up to five potent anti-cancer antibodies.
The combination of these technologies is expected to lead to enhanced potency next generation antibodies and more effective anti-cancer therapies.
Arana will contribute its proprietary protein engineering technologies, Superhumanization and Evogene to generate optimized drug candidates.
Greenovation will then use its Bryotechnolgy, a novel moss-based protein glycol-engineering and production platform to further optimize and produce the antibodies.
Arana chief executive officer Dr John Chiplin said the company was "very excited about the synergy between Arana's and Greenovation's antibody engineering platforms, which together will provide the means to optimize therapeutic antibodies, leading to highly selective and potent drug candidates."
Greenovation chief executive officer Hans Bodo Hartmann said that a "successful feasibility study with Arana" led to the collaboration.
The companies will share the costs of development and commercialization revenues.
Arana climbed 2.5 cents or 2.46 percent to $1.04.

## BIOSIGNAL

Biosignal has placed 4,705,883 shares at 8.5 cents each with an Indonesian based investment group to raise $400,000.

Biosignal chief executive officer Prof Peter Steinberg said the placement achieved two goals.

“It will enable continuing development work at a consistent pace while we finalise the Paul Hawken licences to industrial and wound care applications to be established in the US from the middle of the year,” Prof Steinberg said.

“Second, Indonesia has been targeted by Biosignal as a key territory for early entry to market the oil and gas anti-corrosion product,” Prof Steinberg said.

“This placement strengthens our relationship with groups in Indonesia and introduces another institutional investor to the company,” he said.

Prof Steinberg said the raising and deals announced in March (see Biotech Daily; March 11, 2008) would allow the company to continue its commercial activities to mid-2009.

Biosignal fell two cents or 16.67 percent to 10 cents with 1.8 million shares traded.

## LIVING CELL

Living Cell says it is the first New Zealand company to list its American Depositary Receipts on the International over the counter exchange (OTCQX).

Living Cell said it began trading in the US on June 2, 2008.

The International OTCQX provides non-US publicly-listed companies a gateway to the US securities markets as a vehicle to trade shares with ongoing disclosure to US investors.

Living Cell chief financial officer Richard Justice said that joining the International OTCQX was “a significant milestone”.

Mr Justice said he expected increased liquidity in the company’s shares and the company’s ADRs representing 10 ordinary shares could be traded electronically under the code LVCLY with quotes provided by OTC market makers.

The Bank of New York Mellon is Living Cell’s principal American liaison on the International OTCQX.

Coincident with the listing, Living Cell’s financial information have become available via Standard & Poor's market access program for users of Standard & Poor's Advisor Insight.

Living Cell fell two cents or 5.88 percent to 32 cents.

## BIOPROSPECT

Gun Capital Management and associates have increased their substantial shareholding in Bioprospect from 60,000,000 shares (12.32%) to 70,000,000 shares (14.39%).

The additional shares were bought by Bejjal Pty Ltd at two cents each.

Related parties include Gun Capital Management with 10,000,000 shares, Bejjal with 40,000,000 shares and Leo Khouri with 20,000,000 shares.

Bioprospect was unchanged at two cents.

## INCITIVE

Deckchair Holdings has become a substantial shareholder in Incitive with a holding of 2,785,000 shares or 5.95 percent of the company.

Deckchair Holdings gave an address as care of Pilcher Partners in Perth with Vivienne Jagger as a director.

Incitive was untraded at five cents.

## QRX PHARMA

QRX Pharma has initiated a Level 1 American Depositary Receipt program.
QRX said the ADR program would enable shares to be more accessible to US institutions and private investors, including those permitted to buy only US-based securities.
JP Morgan Chase Bank will operate the program and will act as the depositary bank.
Each ADR will represent five ordinary QRX shares.
The company said the program was part of its strategy "to expand its US investor base, provide greater access to capital markets and increase the liquidity of its stock".
QRX fell two cents or 2.4 percent to 81.5 cents.

## AVANTOGEN

Avantogen says Prof Ian Frazer has been appointed to the scientific advisory board of Hawaii Biotech.
Avantogen said it owned "a bit under 50 percent" of Hawaii Biotech.
Prof Frazer is a leading immunologist and the 2006 Australian of the Year.
Hawaii Biotech is a privately owned vaccine development company based in Honolulu, working on treatments for West Nile virus and Dengue fever.
Avantogen closed up 0.1 cents or 1.06 percent to 9.5 cents.