# Biotech Daily

Tuesday June 2, 2009

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN; OPTISCAN UP 15%, HEARTWARE DOWN 9%**

*** SIRTEX SIR-SPHERES 'SIGNIFICANT BENEFIT' FOR CANCER PATIENTS**

*** CHEMGENEX: MORE PATIENT DATA SUPPORTING OMACETAXINE**

*** CEPHALON 3.45% FROM ARANA COMPULSORY ACQUISITION**

*** BIOPHARMICA, LAING SCREENING FOR FLOPPY BABY SYNDROME CURE**

*** ACRUX: RIVALS WOES, MORE BROKER REPORTS PUSHED PRICE 18%**

*** EASTLAND CONVERTIBLE NOTES RAISE $1.75m**

*** PHARMAXIS REQUESTS CAPITAL RAISING TRADING HALT**

*** CATHRX REQUESTS PROPOSED CAPITAL RAISING TRADING HALT**

*** WHO BUYS 5k ROCKEBY INFLUENZA TESTS**

## MARKET REPORT

The Australian stock market climbed 1.56 percent on Tuesday June 2, 2009 with the S&P ASX 200 up 60.9 points to 3,955.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, four traded unchanged and six were untraded.

Optiscan was best, up 0.7 cents or 15.2 percent to 5.3 cents with 60,000 shares traded, followed by Tyrian up 7.7 percent to 2.8 cents and Benitec up 7.1 percent to three cents.

Psivida climbed 5.6 percent; Viralytics rose 2.8 percent; Cellestis, CSL, Cytopia and Sirtex were up more than one percent; with Arana, Cochlear and Progen up by less than one percent.

Heartware led the falls, down eight cents or 8.7 percent to 83.5 cents with 110,234 shares traded, followed by Living Cell down 7.3 percent to 19 cents.

Genetic Technologies fell 6.15 percent; Polartechnics and Nanosonics lost five percent or more; Biota and Novogen fell more than four percent; Acrux and Phosphagenics were down more than three percent; Bionomics and Prana shed more than two percent; Alchemia, Clinuvel and Genera were down more than one percent; with Circadian, Impedimed, Mesoblast, Peplin and Universal Biosensors down by less than one percent.

SIRTEX MEDICAL

Sirtex says an independent trial has shown that SIR-Spheres with systemic chemotherapy provide significant benefit for end-stage patients with colorectal cancer liver metastases.

Sirtex said the 46 patient multi-centre, randomized, controlled trial demonstrated that the addition of SIR-Spheres microspheres to systemic chemotherapy provided statistically significant clinical benefits for colorectal cancer patients with liver metastases who have exhausted all chemotherapy options.

The trial compared the use of 5-fluorouracil alone to 5-fluorouracil plus SIR-Spheres microspheres and was conducted by a collaboration of university hospitals in Belgium.

Sirtex said selective internal radiation (SIR) therapy was a treatment for inoperable 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 were infused via a catheter into the liver where they selectively target liver tumors with a dose of radiation up to 40 times higher than can be safely delivered by conventional radiotherapy, while at the same time sparing healthy tissue.

Sirtex said the results were reported at the 45th Annual Meeting of the American Society of Clinical Oncology in Orlando, Florida, from May 29 to June 2, 2009.

Sirtex chief executive officer Gilman Wong said the trial demonstrated "the substantial clinical benefits for patients following treatment using SIR-Spheres microspheres".

"This is the first randomized, controlled trial using SIR-Spheres microspheres to be conducted in patients who have failed all available standard-of-care chemotherapy for colorectal cancer liver metastases," Mr Wong said.

"It is also the third randomized controlled trial to provide level one evidence of the safety and effectiveness of SIR-Spheres microspheres, which remains the only product for selective internal radiation therapy that is supported by the results of randomized controlled trials," Mr Wong said.

"The time to progression of disease in the liver - the primary endpoint of the trial - was increased by more than 160 percent, from 2.1 months in patients receiving 5-fluorouracil alone to 5.5 months in those receiving SIR-Spheres microspheres plus 5-fluorouracil (hazard ratio 0.38; 95% confidence interval 0.20 – 0.72; p = 0.003).

Sirtex said significant benefits were also reported in secondary endpoints of the trial.

The time to progression of disease anywhere in the body was also more than doubled, from 2.1 months in the control arm to 4.6 months in patients receiving SIR-Spheres microspheres plus 5-fluorouracil (hazard ratio 0.51; 95% CI 0.28 – 0.94; p = 0.03).

The proportion of patients with disease control increased significantly, from 35 percent to 85 percent, respectively, through the addition of SIR-Spheres microspheres (p = 0.001).

One patient receiving SIR-Spheres microspheres plus 5-fluorouracil had a sufficient reduction in tumor burden to enable potentially curative surgical resection to be conducted.

Following disease progression, 10 patients (43.5%) in the 5-fluorouracil alone arm were allowed to cross over to receive SIR-Spheres microspheres as a salvage therapy and so overall survival was extended in both treatment arms by the targeted treatment of liver tumors. Overall, there was 2.5 months difference in the median survival (7.4 versus 9.9 months) between the 5-fluorouracil and 5-fluorouracil plus SIR-Spheres arms, respectively (hazard ratio 0.92; p = 0.80).

The combination treatment was well tolerated, with significantly fewer patients in the SIR-Spheres microspheres plus 5-fluorouracil arm experiencing a serious adverse event compared to those receiving 5-fluorouracil alone - 4.0 percent compared to 35 percent, respectively (p = 0.02).

Sirtex climbed six cents or 1.98 percent to $3.09.

## CHEMGENEX PHARMACEUTICALS

Chemgenex has published further pivotal trial data supporting its omacetaxine for patients with T315I-positive chronic myeloid leukemia.

Chemgenex said that in an oral presentation and discussion at the 2009 American Society of Clinical Oncology meeting in Orlando, Florida, the number of chronic phase patients treated with omacetaxine mepesuccinate increased from the 25 reported with an 80 percent complete haematological response last year (BD: Dec 9, 2008) to 40 patients with an 85 percent rate for complete haematological response.

The number of patients assessed in the open label phase II/III study increased from 44 in December 2008 to 66 in today's media release of which 40 were in chronic phase, 16 in accelerated phase and 10 in blast phase.

The trial is investigating the use of omacetaxine administered subcutaneously in chronic myeloid leukemia patients who had failed imatinib and who have the drug-resistant T315I kinase domain mutation.

Chemgenex said the median complete haematological response duration in the larger group of patients fell from more than 11.5 months to 8.9 months.

In December, 20 percent of the 25 chronic phase patients (five patients) had major cytogenetic responses, with median response duration of 4.8+ months.

Of today's 40 chronic phase patients, 15 percent (six patients) had major cytogenetic responses, with a median response duration of 6.1 months.

Among accelerated phase patients Chemgenex said there was a complete haematological response rate of 31 percent with a median duration 4.1 months and a major cytogenetic response rate of six percent with a median response duration 1.8 months.

Among blast phase patients the complete haematological response rate was 20 percent with a median duration of 3.3 months.

Chemgenex said that the investigators reported omacetaxine was generally well tolerated, and that the most common side effect was reversible and transient myelo-suppression.

The deputy chair in the Department of Leukemia at the University of Texas MD Anderson Cancer Center and the study's lead investigator Prof Jorge Cortes said omacetaxine was "well-tolerated in this study and durable hematological and cytogenetic responses were observed in some CML patients with the T315I mutation".

"Several novel drugs have already been investigated in this difficult-to-treat population, but they have not had a reasonable risk to benefit ratio," Prof Cortes said.

"These results suggest that omacetaxine may represent the first viable treatment option for this population of patients who currently have no established treatment options," Prof Cortes said.

Chemgenex's chief executive officer Dr Greg Collier said the data was "a very important milestone" for both omacetaxine and Chemgenex.

Dr Collier said the data would be provided to the US Food and Drug Administration for the new drug application submission, which was on-target for completion by October 2009.

Chemgenex jumped 6.5 cents or 11.6 before closing up half a cent or 0.89 percent at 56.5 cents with 1.3 million shares traded.

## ARANA

Cephalon is within 10 million acceptances (3.45%) of the compulsory acquisition of Arana.

Yesterday Cephalon extended its takeover offer for Arana to 7pm on June 15, 2009.

Today Cephalon said the number of acceptances increased from 182,413,493 shares (80.01%) to 197,323,160 (86.55%) on June 1, 2009.

Arana was up one cent or 0.72 percent to $1.39.

## BIOPHARMICA

Biopharmica and the Laing Neuromuscular Diseases Group are collaborating to screen compounds to increase heart actin in skeletal muscles to treat 'floppy baby syndrome'.
Biopharmica said that "in a world first" its wholly owned subsidiary Molecular Discovery Systems and the Laing Group "cured mice" of a muscle disease that causes floppy baby syndrome, a congenital myopathy disorder that causes babies to be born without the ability to properly use their muscles.
The research has been published online in the Journal of Cell Biology and is available at http://jcb.rupress.org/cgi/content/full/jcb.1855iti2v1.
The lead author Dr Kristen Nowak said the data was a proof of principle and the collaboration with Molecular Discovery allowed the screening of more than 1,000 already approved medications.
The collaboration was looking for a compound that increases heart actin in skeletal muscles.
The genetic disease renders most of the affected children severely paralyzed and takes the lives of many of these children before the age of one year. It is presently incurable.
Both Molecular Discovery and the Laing Neuromuscular Diseases Group are located in the Western Australian Institute for Medical Research and have been collaborating through a French Muscular Dystrophy Association grant since 2008.
Biopharmica said Molecular Discovery had core expertise in high content and high throughput imaging and analysis.
The company said its Incell Analyzer 1000 was a high-content screening platform designed for the rapid throughput and analysis of cell culture screens in multiple-well formats and was similar to those used for large-scale drug screens.
Biopharmica said it was "ideally suited" to screen of off-label drug effects that up-regulate cardiac actin in the Flexor Digitorum Brevis culture system that the Laing Group developed.
Biopharmica was unchanged at 3.5 cents.

## ACRUX

Acrux has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.
Acrux said that more analysts, Wilson HTM, Shaw Stockbroking and BBY have upgraded the company's target share price and the previously discussed issues involving transdermal rivals and impending phase III trial results may have led to a jump in share price.
The ASX said the company's share price rose from $1.21 on May 29, 2009 to $1.33, an 18.18 percent increase, on June 1, 2009, but did not note an increase in trading volume.
Acrux climbed 95.8 percent to $188 million in the month of May and was questioned by a 19.8 percent increase earlier in May. (BD: May 12; June 1, 2009).
Acrux said that on May 7, 2009 ABN Amro Morgans' analyst report upgraded its recommendation from 'hold' to 'buy, with a target price of $1.05 and a valuation of $1.75 a share. The company said that at that time the US US Food and Drug Administration was investigating side effects associated with competitor drugs.
Acrux was cents or percent to cents.
Acrux also told the ASX today, that its loss for the year to June 30, 2009 might vary by more than 15 percent from the previous corresponding period but the company did not believe that was "material to share trading at this stage".
Acrux fell five cents or 3.7 percent to $1.30.

## EASTLAND MEDICAL SYSTEMS

Eastland Medical has raised $1.75 million through the issue of $1.00 convertible notes with a six percent interest rate repayable by June 30, 2012.
The notes convert at three cents a share at any time after December 21, 2009 until the maturity date.
Eastland said investors who bought into a convertible note for $480,000 in January have agreed to cancel their respective convertible note subscriptions and enter into the new convertible note deeds.
Eastland said about $1.0 million of the convertible note was conditional on the company raising $5.2 million, with the rights issue and share placement (BD: May 25, 2009).
The funds are for working capital, debt reduction and to support the commencement of the Artimist trial in Africa.
The company said that on March 3, 2009 the company also advised that a mandate had been secured with RM Corporate Finance to arrange $4.0 million to $6.0 million.
Eastland said the mandate had closed and the company appointed Patersons Securities to be the lead managers for the one-for-two non-renounceable rights issue at three cents to raise up to $3.28 million and the placement of 19.5 million shares at three cents each to raise $585,000.
Eastland was up 0.2 cents or 4.55 percent to 4.6 cents.

## PHARMAXIS

Pharmaxis has requested a trading halt pending an announcement in relation to a capital raising.
Trading will resume on June 4, 2009 or on an earlier announcement.
Pharmaxis last traded at $2.63.

## CATHRX

Cathrx has requested a trading halt pending an announcement in relation to a proposed capital raising.
Trading will resume on June 4, 2009 or on an earlier announcement.
Cathrx last traded at 50 cents.

## ROCKEBY BIOMED

Rockeby says the World Health Organisation has ordered 5000 human influenza test kits to be supplied in the month of June 2009.
Rockeby said it was “the first time that Rockeby … has supplied its products to WHO and highlights WHO’s recognition of the company’s products”.
The company said its human influenza A rapid test could be used for testing the human H1N1 influenza.
Rockeby was up 1.2 cents or 38.7 percent to 4.3 cents.