



Biotech Daily

Tuesday June 9, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN; CATHRX UP 31%, TYRIAN DOWN 14%**
- * **CSL QUILTS TALECRIS, CITES US FTC, \$95m BREAK FEE; BUY-BACK**
- * **FDA REQUIRES EXTRA PEPLIN PHASE III TRIAL; TWO MORE BEGIN**
- * **CHEMGENEX DRUG EFFECTIVE FOR MULTIPLE RESISTANT LEUKEMIA**
- * **CHEMGENEX'S OMACETAXINE KILLS LEUKEMIC STEM CELLS**
- * **BONE FILES ORAL OSTEOPOROSIS DRUG IND TO FDA**
- * **GENETIC TECHNOLOGIES' IMMUNAID MAKES CANCER DOSE PROGRESS**
- * **GENERA EGM TO VOTE ON PLACEMENT, DIRECTORS' SHARES, OPTIONS**
- * **NEURODISCOVERY APPOINTS HARRY KARELIS DIRECTOR**
- * **ROCKEY APPOINTS EDWIN BOYD DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.92 percent on Tuesday June 9, 2009 with the S&P ASX 200 down 36.3 points to 3,934.9 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and five were untraded.

Cathrx was best, up 12 cents or 30.8 percent to 51 cents with 28,200 shares traded, followed by Novogen up 16.1 percent to 86.5 cents and Nanosonics up 13.8 percent to 53.5 cents.

CSL and Living Cell climbed more than five percent; Starpharma was up 4.6 percent; Alchemia, Progen, Resmed and Viralytics rose more than two percent; Mesoblast was up 1.8 percent; with Heartware up 0.6 percent.

Tyrian led the falls, down 0.4 cents or 14.3 percent to 2.4 cents with 41.7 million shares traded, believed to be QIC exiting the company.

Peplin fell 9.8 percent; Benitec, Genera, Impedimed and Optiscan lost six percent or more; Acrux, Avexa and Cytopia fell four percent or more; Biota and Phosphagenics were down more than three percent; Cochlear shed 2.1 percent; with Clinuvel, Genetic Technologies and Pharmaxis down more than one percent.

CSL

The \$US3.1 billion CSL-Talecris Biotherapeutics merger has been cancelled and CSL will pay Talecris a \$US75 million (\$A95.1 million) break fee.

CSL chief executive officer Dr Brian McNamee said in a media release that he was “disappointed that the US Federal Trade Commission resolved to block the transaction”. Last month the US Federal Trade Commission began legal action to prevent CSL’s proposed acquisition of Talecris (May 28, 2009).

Dr McNamee said at that time: “The FTC has failed to recognize that this combination is pro-competitive, provides significant efficiencies that will improve the supply of biotherapies and is beneficial to the patient community.”

Dr McNamee said the FTC’s complaint was more about the dynamics of the sector than CSL’s size. He said the FTC had a theory of “coordinated behavior” with which CSL strongly disagreed.

Today, Dr McNamee said: “We fundamentally disagree with the FTC case and matters included in their complaint”.

He said CSL believed in the customer benefits and financial synergies that supported the transaction, but the directors “did not believe that entering into a protracted litigation process with the FTC, with its inherent risks, substantial costs, and lengthy distraction of CSL management and staff from planning and running our businesses would be in the best interests of our stakeholders.”

CSL announced a share buy-back, offering \$29 a share to buy back up to 54,863,000 shares. If fully subscribed the buy-back would return \$1.591 billion to shareholders.

To raise funds for the Talecris deal, CSL placed 47.5 million shares at \$36.75 a share to raise \$1.75 billion from institutional investors (BD: Aug 14, 2008) and a share plan at the same price raised \$145 million (BD: Sep 19, 2008).

CSL climbed \$1.51 or 5.2 percent to \$30.49 with 8.6 million shares traded.

PEPLIN

Peplin says the US Food and Drug Administration wants a further non-head phase III trial along with two phase III trials of PEP005 gel for actinic keratoses on the face and scalp. Peplin chief executive officer Tom Wiggans said that based on the data generated so far, PEP005 gel or ingenol mebutate and its short course of therapy “represents a significant advance in the treatment of a common skin condition, which if left untreated can progress to squamous cell carcinoma”.

He said the new phase III trials were important as they include the face and scalp areas, which comprise an estimated 70 percent of the actinic keratoses market and have the potential to provide the most patient benefit.

Peplin said that as a result of an end-of-phase II meeting with the US Food and Drug Administration, the company will conduct an additional phase III pivotal trial on non-head locations, which includes the trunk and extremities, to corroborate the results of the recently completed phase III trial.

Peplin said there would be a total of four phase III trials: the two newly initiated head trials (Region-IIa and Region-IIb), the recently completed non-head trial (Region-Ia) and the upcoming non-head trial (Region-Ib).

Peplin said its current cash would be sufficient to fund the completion of phase III testing and plans to file a new drug application in mid-2010.

Peplin fell 6.5 cents or 9.77 percent to 60 cents.

CHEMGENEX

Chemgenex says chronic myeloid leukemia patients with resistance to multiple tyrosine kinase inhibitors have responded positively to its omacetaxine mepesuccinate.

Chemgenex said data from its phase II/III trial study of omacetaxine for patients with resistance to multiple tyrosine kinase inhibitors was presented at the European Hematology Association meeting in Berlin on Saturday by the chief of the leukemia division at the University at Buffalo, Roswell Park Cancer Institute's Dr Meir Wetzler. The data presented was from 65 patients of which 30 were in chronic phase, 20 in accelerated phase and 15 in blast phase.

Of the chronic phase patients 80 percent had a complete hematologic response with a median response duration of 7.5 months

The chronic phase patients had a major cytogenetic response rate of 20 percent with a median response duration 2.7 months

Sixty percent of accelerated phase patients had a complete hematologic response with a median duration 8.9 months and 40 percent of Blast phase patients had a complete hematologic response with a median duration 5.7 months

Investigators reported that omacetaxine was generally well tolerated and that the most common side effect was reversible and transient myelosuppression.

A lead investigator in the study, Dr Wetzler said tyrosine kinase inhibitors were the "front line of attack" in chronic myeloid leukemia, but significant numbers of patients developed cross resistance to drugs in this chemical class.

Chemgenex chief executive officer Dr Greg Collier said Omacetaxine had "a very different mechanism of action" compared to the tyrosine kinase inhibitors (TKIs).

"We have always believed that it may offer the potential to overcome TKI-resistance," Dr Collier said. "The latest results of this study are very encouraging, but this clinical trial is still at an early stage."

Chemgenex was unchanged at 56.5 cents.

CHEMGENEX

Chemgenex says pre-clinical research has demonstrated that omacetaxine kills model human leukemic stem cells.

Chemgenex chief financial officer Dr James Campbell told Biotech Daily the leukemic stem cells from humans with chronic myeloid leukemia (CML) were grown in culture in a laboratory.

Chemgenex said human leukemic stem cells were known to be insensitive to tyrosine kinase inhibitors (TKIs), the drug family approved to treat chronic myeloid leukemia.

The data, developed in collaboration with the University of Glasgow, was presented by the clinical scientist of the Scottish National Blood Transfusion Service Elaine Allan at the European Hematology Association in Berlin, Germany on Sunday.

Ms Allan said currently licenced drugs "target and disable the diseased cells in the blood stream and bone marrow, but they have little, if any, effect on the primitive leukemic stem cells that are at the root of this blood cancer".

"In contrast, we have shown omacetaxine to be not only anti-proliferative, but also to induce apoptosis in human CML stem cells," Ms Allan said.

The chairman of the department of leukemia at the University of Texas M D Anderson Cancer Center, Prof Hagop Kantarjian said the study results were "exciting".

"These results raise the possibility of eradicating the dormant malignant stem cells that are thought to be responsible for relapse in CML patients who discontinue TKIs," Dr Kantarjian said.

BONE MEDICAL

Bone has filed its investigational new drug application for oral Capsitonin for osteoporosis with the US Food & Drug Administration.

Bone said the IND application for Capsitonin, or salmon calcitonin, included a request for agreement to the design for a late stage clinical trial.

The company said that once this was clarified and accepted it would proceed to manufacturing with the appropriate documentation to be lodged with the agency prior to patient recruitment and dosing.

Bone chairman Leif Jensen said the IND filing milestone involved substantial documentation and was the culmination of six years of preclinical and phase I and II clinical testing.

The company said Capsitonin had a significant second indication of treating pain associated with osteoarthritis.

Bone said the market for osteoarthritis pain had fewer treatment choices since Vioxx was withdrawn from the market.

The company said that calcitonin was known to be "very safe over prolonged usage" and could have a large market impact if proven effective in the oral form.

Bone said Capsitonin worked by increasing calcitonin in bones, the body's own hormone responsible for strong and healthy bones. It has been safely administered as an injectable for more than 30 years and more recently as a nasal spray.

Bone was unchanged at 18 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says subsidiary Immunaid has made progress with its hypothesis that dosing cancer patients could be linked to C-reactive protein levels.

Genetic Technologies said it owned its 69.2 percent of Immunaid a private Australian cancer company hypothesizing that the immune system exhibits dynamic characteristics.

Genetic Technologies told Biotech Daily the originator of the hypothesis Martin Ashdown owned most of the remaining 30.8 percent along with several early supporters.

The company said at the American Society of Clinical Oncology conference in Orlando, Florida, investigators at the Mayo Clinic Rochester reported on a pilot trial entitled 'Possible therapeutic reversal of immune suppression in patients with metastatic melanoma by timed delivery of temozolomide chemotherapy'.

Genetic Technologies said the pilot study was designed using Immunaid's concept for timed intervention with chemotherapy.

Over a two week period, 12 patients were measured daily for C-reactive protein (CRP) levels. The company said that CRP levels oscillated with an average periodicity of 7.8 days. Dosing of temozolomide at 200mg/m² for five days for every 28 days was initiated. Two patients who were treated before the peak in CRP levels remained progression-free for greater than two years, while all other patients, excluding one who dropped out early, were treated post-CRP peak levels and had disease progression.

Genetic Technologies chief executive officer Dr Paul MacLeman said the early results "suggest that the Immunaid approach to unlocking control of the effector part of the immune system from control by the regulatory branch, leading to a successful attack on tumor cells by co-opted immune system attack cells, may be a useful approach in treating cancer".

This approach is undergoing further assessment in a trial at Melbourne's Royal Women's Hospital.

Genetic Technologies fell 0.1 cents or 1.64 percent to six cents.

GENERA BIOSYSTEMS

Genera investors will vote on the prior allotment of 6,975,000 placement shares along with 500,000 shares and 550,000 options to directors.

The prior allotment was to placement investors who paid 40 cents a share (BD: May 19, 2009).

The meeting will consider the issue of 300,000 options to director Mel Bridges and 250,000 options to director David Symons.

Genera investors will vote on the issue of 100,000 placement shares to chairman Fernando Careri, 25,000 placement shares to director Dr Karl Poetter and 375,000 placement shares to director Bill Tapp or his nominee Ag-Sun Technologies.

The meeting will be held at Grant Thornton Audit, Level 2, 215 Spring Street, Melbourne, on July 10, 2009 at 11am.

Genera fell four cents or 6.78 percent to 55 cents.

NEURODISCOVERY

Neurodiscovery says Harry Karelis has been appointed a director.

The company said Mr Karelis represents its major shareholder Biotech Capital.

Neurodiscovery said Mr Karelis was the founder and managing director of Titan Bioventures Management, the investment manager of Biotech Capital.

Mr Karelis has led investments in drug discovery, regenerative medicine, medical devices and several other technology platform areas.

The company said Mr Karelis graduated from the University of Western Australia with a Bachelors of Science (Hons) majoring in biochemistry and microbiology as well as a Masters in Business Administration.

Neurodiscovery was untraded at 3.3 cents.

ROCKEBY

Rockeby has appointment of Edwin Leith Boyd as a director effective from June 1, 2009.

Rockeby made the announcement after the market closed on June 5, 2009.

The company said Mr Boyd had "extensive executive, financial and directorial expertise across a range of industries including food and beverage, franchising, corporate services and resources.

He holds directorships in public and private companies.

Rockeby was unchanged at 3.8 cents.