Biotech Daily

Tuesday October 5, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 7%; CATHRX DOWN 13%**

*** CHEMGENEX OMAPRO NDA DELAYED UP TO 12 MONTHS, WITH CLARITY**

*** CHEMGENEX PLEADS SCHULTZ TO ASX 41% PRICE JUMP QUERY**

*** FLUOROTECHNICS SELLS US SUBSIDIARY, THE GEL CO**

*** BIONOMICS FRENCH TRIALS FOR PANIC ATTACKS, MEMORY LOSS**

*** TISSUE THERAPIES APPOINTS US COMMERCIALIZATION CONSULTANT**

*** ACRUX WINS TWO VICTORIA GOVERNOR EXPORT GONGS**

MARKET REPORT

The Australian stock market fell 0.4 percent on Tuesday October 5, 2010 with the S&P ASX 200 down 18.4 points to 4606.9 points.

Eight of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and nine were untraded. All three Big Caps were up.

Pharmaxis was best, up 16 cents or 7.4 percent to $2.32 with one million shares traded, followed by Tissue Therapies up 4.4 percent to 23.5 cents with 309,000 shares traded.

Living Cell climbed three percent; Phylogica and Psivida both rose 2.04 percent to five cents and $5, respectively; Acrux, Phosphagenics and Starpharma were up more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Cathrx led the falls, down 3.5 cents or 13.2 percent to 23 cents with 20,000 shares traded, followed by Sunshine Heart down 0.3 cents or 10 percent to 2.7 cents with 19,500 shares traded.

Optiscan lost 6.8 percent; Benitec was down 5.6 percent; Cellmid, Novogen and Prima fell four percent or more; Viralytics was down 3.1 percent, with Biota and Impedimed down more than two percent.

CHEMGENEX

Chemgenex says that following a meeting with the US Food and Drug Administration its new drug application for Omapro had been delayed for up to 12 months.

Chemgenex chief operating office Dr James Campbell told Biotech Daily that although the company had hoped to file the new drug application for Omapro for chronic myeloid leukemia by December 31, 2010 and that had been set back by "six to 12 months", the company had a formal letter from the FDA saying no more clinical trails would be required.

Dr Campbell said the FDA would require further follow-up data from the two trials of Omapro or omacetaxine mepesuccinate for chronic myeloid leukemia patients who had developed the T315I mutation and were resistant to Gleevec (imatinib), as well as those who had failed two or more tyrosine kinase inhibitors.

In a media release Chemgenex said new drug application was for the latter indication, but could include data from the T315I mutation trial.

"It was agreed that no further clinical trials are required to complete this NDA submission, however further data will need to be collected from participating clinical centres," the Chemgenex media release said.

Chemgenex said that based on the timing required for collection of the additional data, the application for Omapro for the treatment of chronic myeloid leukemia patients who failed two or more tyrosine kinase inhibitors regardless of their mutation status, would be submitted in the second half of 2011.

Earlier this year the FDA criticized the Chemgenex application for approval for the T315I mutation (BD: Feb 9, Mar 23, Apr 12, 2010)

Chemgenex was unchanged at 48 cents with four million shares traded.

CHEMGENEX

Chemgenex says it is not aware of any information that has not been announced which, if known, could be an explanation for recent trading in its securities.

The ASX said the company's share price climbed 14 cents or 40.68 percent from 34.5 cents on September 30, 2010 to 48.5 cents on October 4, 2010, but did not note an increase in trading volumes.

Chemgenex said it was possible that its operating results for the six months to December 31, 2010 could vary by more than 15 percent from the previous corresponding period and cited the Hospira agreement for the licencing of Omapro in Europe.

The company also noted that it had released today's announcement (above) detailing the pre-new drug application meeting with the US FDA, but said it did not believe the release provided an explanation for the recent trading in its shares.

FLUOROTECHNICS

Fluorotechnics says it has sold its US subsidiary the Gel Company as part of the scaling back of its operations and selling some or all of its assets.

Fluorotechnics said the cause of sale was the disappointing revenues from the Northern Hemisphere "due to the global financial crisis".

The company said the sale's financial results would be in the 2010 annual report.

Fluorotechnics said it was continuing to review other opportunities for the orderly sale of the remaining operations and assets.

Separately, the company said that 8,642,125 shares and 3,151,000 options would be released from escrow on October 30, 2010.

Fluorotechnics has been suspended from trading and last traded at 3.8 cents.

BIONOMICS

Bionomics says it has French regulatory and ethics approval for two advanced phase I clinical trials to study BNC210 for panic attacks and comparative memory loss.

Approved by the regulator, Agence Francaise de Securite Sanitaire des Produits de Sante and the ethics committee of the Strasbourg Hospital, Bionomics will examine whether BNC210 reduces panic and anxiety symptoms induced by pharmacological means in 22 healthy volunteers.

Bionomics said the peptide CCK-4 would be used to induce symptoms of panic and anxiety and in a rodent model of induced anxiety, BNC210 overcame the effects of CCK.

Bionomics said the second trial would evaluate the effects of BNC210 on the brain using electroencephalograph (EEG) and quantitative assessments of memory function.

The company said that in the randomized, double-blind, 24-patient, four-way, cross-over trial BNC210 would be compared with Lorazepam, a drug closely related to Valium, which had the adverse side effect of causing memory impairment.

Bionomics said the trials would be conducted in France by the contract research organization Forenap Pharma, which would run both clinical studies in parallel, with data expected by April 2011.

Bionomics chief executive officer Dr Deborah Rathjen said the trials were “a major step forward in the development of BNC210 for the treatment of anxiety disorders”.

“Our previous phase I clinical trials indicated that BNC210 was safe and well tolerated and with no indication, even at high dosage levels, of the side effects found in many currently available drugs used to treat anxiety,” Dr Rathjen said.

“Whilst these new clinical trials will be conducted in healthy volunteers, both studies have been specifically designed to demonstrate the value of BNC210 as an innovative treatment for anxiety and depression,” Dr Rathjen said.

Bionomics said panic disorder was a common anxiety disorder experienced by 1.7 percent of the population and was treated with benzodiazepines such as Valium and Xanax.

The company said Xanax was the first drug approved for panic attacks, was the most prescribed psychiatric drug in the US, with one prescription issued every second in 2009.

“Bionomics’ trials of BNC210 will investigate the potential of BNC210 to relieve symptoms of panic and anxiety,” Bionomics said.

“They will also evaluate the brain effects of BNC210 compared to Lorazepam, another benzodiazepine, which is known to impair memory,” Dr Rathjen said.

“The potential commercial implications of positive results in these two trials cannot be overstated,” Dr Rathjen said.

Bionomics was unchanged at 27 cents.

TISSUE THERAPIES

Tissue Therapies has appointed consultant Geoff Morris to assist in commercial partner negotiations for Vitrogro for acute and chronic wound healing products.

Tissue Therapies said the US-based Mr Morris was a former executive of the US healthcare industry, with experience in international large corporates and consulting.

Tissue Therapies chairman Roger Clarke said the company was “particularly pleased to have the assistance of Mr Morris to advance our negotiations to a conclusion with a number of prospective commercialization partner health care companies”.

“Our objective is to establish an agreement with the health care partner that is best positioned to transform the wound care market with a new generation of Vitrogro products,” Mr Clarke said.

Tissue Therapies was up one cent or 4.4 percent to 23.5 cents.

ACRUX

Victoria's Industry and Trade Minister Jacinta Allan says Acrux has won the Governor of Victoria Export Awards for Innovation Excellence and the Large Services Export Award.

A media release from Ms Allan said Acrux range of fast-drying, invisible transdermal technology "exemplified the kind of innovation that helped position Victoria as a global leader in biotechnology".

"Biotechnology is one of the world's fastest growing industries and I congratulate Acrux on their outstanding success in this highly-skilled and highly competitive sector," Ms Allan said.

"The company's products are used to treat conditions such as hormonal deficiencies and central nervous system disorders, as well as for contraception, and are designed to be preferred by patients over current therapies, such as painful injections or the ingestion of multiple tablets," Ms Allen said.

The media release said Acrux's commercial focus was entirely on export markets.

Last year, the Australian Therapeutic Goods Administration required Acrux to provide more data on its estradiol spray Ellavie marketed in the US since 2008 as Evamist.

The company said last year that the TGA wanted supporting data that compared the spray to an Australian marketed estradiol transdermal product and the value of the Australian market for Ellavie was small.

Acrux chief executive officer Dr Richard Treagus said the Governor of Victoria Export Awards followed a successful year for the company and were further testimony to its hard work and dedication since inception 10 years ago.

"This year has been an incredible year for Acrux with the company posting an exceptional maiden profit and signing the largest product licencing deal in the history of Australian biotechnology," Dr Treagus said.

"Acrux has effectively developed, patented and commercialised a Victorian technology invented at Monash University," Dr Treagus said.

Acrux was up four cents or 1.7 percent to $2.38.