Biotech Daily

Thursday May 6, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN:**
VIRALYTICS UP 10%; PHYLOGICA, SUNSHINE HEART DOWN 11%

*** FDA DELAYS COST CHEMGENEX OMAPRO 12 MONTHS**

*** NEUREN BEGINS PHASE II NZ2566 US 260-PATIENT BRAIN INJURY TRIAL**

*** VICTORIA: PLATYPUS PEPTIDES AS ANTIMICROBIALS**

*** FLUOROTECHNICS SELLS SYSTEM TO YALE**

*** BIONOMICS TRIALS BNC210 ANTI-ANXIETY DRUG EFFECT WITH FOOD**

*** NYCOMED TO DISTRIBUTE IMMURON'S TRAVELAN FOR DIARRHOEA**

*** SUN BIOMEDICAL TO SAVE OCCUPATIONAL & MEDICAL**

*** AVEXA REQUESTS APRICITABINE TRADING HALT**

MARKET REPORT

The Australian stock market fell a further 2.16 percent on Thursday May 6, 2010 with the S&P ASX 200 down 100.8 points to 4573.2 points.

Seven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and seven were untraded.

Viralytics was best, up 0.4 cents or 10 percent to 4.4 cents with 2.1 million shares traded, followed by Prana up half a cent or three percent to 17 cents with 175,500 shares traded.

Heartware, Nanosonics, Pharmaxis and QRX rose more than two percent, with Cochlear, CSL and Living Cell up one percent or more.

Phylogica and Sunshine Heart led the falls, down 11.1 percent to eight cents and 3.2 cents, respectively, on modest volumes.

Cellmid and Phosphagenics lost more than seven percent; Prima fell 6.7 percent; Tissue Therapies was down 5.6 percent; Biota and Cellestis fell more than four percent; Alchemia, Sirtex and Starpharma shed more than two percent; with Bionomics, Chemgenex, Circadian, Impedimed and Universal Biosensors down more than one percent.

CHEMGENEX

Chemgenex chief executive officer Dr Greg Collier says delays to answer US Food and Drug Administration (FDA) questions could delay Omapro approval by 12 months.

Speaking to an investor teleconference, Dr Collier said the next step in the approval process for the company's lead product omacetaxine mepesuccinate (Omapro) was a meeting with the FDA.

Omapro is being developed to treat chronic myeloid leukemia patients who have failed on Gleevec and have the T315I mutation.

In March 2010, a meeting of the FDA's Oncologic Drugs Advisory Committee required Chemgenex to validate a diagnostic test to ensure that the patients had the T315I mutation to ensure that false positives did not miss out on second line treatments before progressing to Omapro (BD: Mar 23, 2010).

Last month the FDA sent Chemgenex a complete response letter, requiring the company to address the diagnostic issue, a lack of data and a problem with the vial containing the drug (BD: April 12, 2010).

The company's share price fell as much as 62 percent on the first announcement and has not recovered significantly.

Today, Dr Collier said the Oncologic Drugs Advisory Committee only voted on the question of a diagnostic test and the leukemia experts on the Committee said publicly that if the vote was on safety and efficacy, they would have voted for it.

Dr Collier said the next step would be "a Type A meeting with the FDA" which the company would request "any day now" and the FDA had 30 days to respond putting the meeting into June.

Dr Collier said the company would have the opportunity to discuss the issues at that time.

He said the data package was strengthened over time and in December 2009 the company presented 81 patient data at American Society of Hematology (BD: Dec 7, 2009) and had data on 103 patients, compared to the 66 in the original new drug application package.

Dr Collier said he had been working with a division of the FDA on selecting the appropriate T315I diagnostic test or tests.

Dr Collier said that the timeline for European approval was "on target" and expected feedback at the end of 2010 for a possible approval in early 2011.

"This is an unmet need," Dr Collier said. "We want to move quickly for these patients."

"There is no suggestion that we need to do a new clinical trial," Dr Collier said.

He said that should all go well at the FDA Type A meeting it would take "an additional several months" to complete the review.

Dr Collier said ODAC was confused over the study design and inclusion criteria.

"All patients had to come to the trial with confirmation that they had the T315I mutation," Dr Collier said. "We have to show that false positives are unlikely and that needs to be addressed."

Dr Collier said that about 30,000 people in the US had chronic myeloid leukemia and provided percentages that implied that about 1200 had the T315I mutation. At $80,000 per patient per year for other treatments, Chemgenex should earn $96 million a year from this first indication, alone.

Asked why two patients had not had bone marrow aspirations performed as per the FDA protocol, a point made in notes to the ODAC committee by the FDA, Dr Collier said he still did not know the answer.

As recently as December 2009, Chemgenex was expecting US and European approval this year.

Chemgenex fell half a cent or 1.35 percent to 36.5 cents.

NEUREN PHARMACEUTICALS

Neuren says it has begun recruitment for its 260-patient phase II clinical trial of NNZ-2566 for moderate to severe brain injury in collaboration with the US Army.

Neuren said the Army was covering the majority of direct costs of the trial, designated Intrepid2566.

The company said 12 US "level I and II trauma centres" were expected to participate as clinical trial sites, with the University of Miami the first to become fully operational.

Neuren said the University of Miami's principal investigator was Prof M Ross Bullock, a member of the Neuren-US Army Advisory Committee and the second operational site was Arrowhead Regional Medical Center in Colton, California with Dr Javed Siddiqi the principal investigator.

Neuren said patients would be randomized two-to-one for drug and placebo and the study would examine safety, patient function, neuropsychological measures and physiological assessments through electroencephalograph monitoring and serum-based biomarkers. Enrolment is expected to take 18 months.

Neuren said it would conduct additional preclinical and clinical studies necessary for a pivotal or registration trial, including reproductive toxicology studies in animals, a cardiovascular safety study in human volunteers and a safety and pharmacokinetics study in female volunteers, a requirement for enrolling women in the phase II and other trials.

Neuren said the reproductive toxicology studies had been initiated as had the safety and pharmacokinetics study in females which was being conducted at Nucleus Network's Centre for Clinical Studies in Melbourne and the first cohort of the safety and pharmacokinetics study has been completed with no adverse events reported.

Neuren's chief executive officer Larry Glass said the company was "delighted that this critically important and ambitious trial is now off the ground".

"Getting to this point has required great dedication and a concerted effort on the part of the company's staff, consultants and collaborators not to mention patience and commitment on the part of our investors," Mr Glass said.

"Knowing that, between the financing announced at the end of 2009 and funding from the US Army, we have access to all of the capital resources needed to complete the study contributes significantly to our level of confidence," Mr Glass said.

Neuren said the trial was delayed by the need to develop a buffer system for reconstitution of the drug.

In the phase Ib study, injection site reactions occurred in some patients receiving higher doses for longer periods and the reactions were believed to result predominantly from the acidity (pH 3.7) and concentration of the drug, the company said.

While the reactions were not classified as serious adverse events and were not raised by the FDA as a safety issue, the company said it was concerned that their appearance could make it obvious to clinical staff which patients were receiving the drug, with the risk of inadvertently unblinding the study.

Neuren said it had developed a buffer system that produced an infusion solution with normal physiologic pH and osmolarity which had been provided to the clinical sites along with the drug product for use in the trial. It had been used in the first cohort of the safety and pharmacokinetics study noted above with no adverse events reported.

Neuren said development work on drug manufacturing was ongoing with a 30-35 percent increase in yield for clinical batches already achieved as well as a targeted reduction in impurities.

Neuren has struggled to recover from a failed Glypromate trial in 2008 (BD: Jan 16, 2009), despite other work continuing, a company reorganization and funds becoming available.

Neuren was up 0.2 cents or 6.7 percent to 3.2 cents.

VICTORIA GOVERNMENT

Victoria's Agriculture Minister Joe Helper says the platypus could hold the key "to finding a new generation of medicines to kill off drug-resistant superbugs".

Mr Helper said Department of Primary Industries' scientists were the first to isolate, synthesize and test a number of platypus proteins, leading to the discovery of several new antimicrobials.

"We already know these platypus antimicrobials are 10 times more potent in killing bacteria than some of their antimicrobials commonly used with humans," Mr Helper said.

"If we can harness some of this potential we could better protect patients from superbugs, meaning they will recover from surgery faster and spend less time in hospital," he said.

Mr Helper said the discovery was remarkable, where the protein-encoding genes of an ancient animal - the platypus - were being used to potentially create natural but highly effective new medicines or treatments.

"The platypus species evolved more than 180 million years ago and still retains a number of even older traits - such as egg laying - that have been passed down from mammal-like reptiles that lived 300 million years ago," Mr Helper said.

"Over many centuries, platypus have developed a very enhanced natural immunity, which may help their offspring survive a challenging environment while still very young, Mr Helper said.

Mr Helper said the discovery could be used to combat animal and plant diseases, and potentially treat antibiotic-resistant bacterial infections in humans.

The Department of Primary Industries' deputy secretary Dr Bruce Kefford said the genes analyzed by Victorian scientists in conjunction with colleagues at the University of Sydney led to the production of antimicrobial peptides.

"DPI scientists are already putting their discovery to work to improve the efficiency of our livestock industry," Dr Kefford said.

"If introduced into the stomachs of cattle, these platypus antimicrobials could improve an animal's digestion of feed and reduce methane production, one of Australia's largest contributors of total greenhouse gas emissions."

FLUOROTECHNICS

Fluorotechnics says Yale University has adopted its high performance electrophoresis (HPE) flat top tower system.

Fluorotechnics announced the sale in a media release but did not report it to the ASX.

Last month Fluorotechnics also announced by media release, but not to the ASX, that the Germany-based Max Planck Institute of Biochemistry adopted its HPE Flat Top Tower System for protein analysis work (BD: Apr 21, 2010).

The co-director of Yale's WM Keck Foundation Biotechnology Resource Laboratory Dr Terence Wu was quoted by the company saying he was attracted to the HPE system "because of its high performance, robust construction and relatively low operating cost".

Fluorotechnics chief executive officer James Walker said the HPE system's debut into the US market was "just the start of the product's success".

"We are proud to be working with Dr Wu and the professional team at Yale University, one of the world's leading research institutions," Mr Walker said in the press release.

"We think this endorsement is a great validation of our approach to improving proteomics research and we look forward to continuing that," Mr Walker said.

Fluorotechnics was untraded at 17.1 cents.

BIONOMICS

Bionomics has begun a second phase I trial of anti-anxiety compound BNC210, to determine whether administration with food alters blood levels of the drug.
Bionomics said the trial was expected to be completed in June and was “an important lead-in to phase Ib clinical trials” expected to commence shortly after.
The company said the trial would be conducted in a group of healthy male volunteers at the Royal Adelaide Hospital’s Pain and Anaesthesia Research Clinic with Prof Paul Rolan as principal onvestigator.
Bionomics chief executive officer Dr Deborah Rathjen said that many orally administered drugs were taken either with food or following a meal and it was important to determine how food intake affected blood levels of the drug.
“Bionomics is able to quickly and cost-effectively undertake this trial to pharmaceutical industry standards and, in doing so, will add value to the licensing package for BNC210,” Dr Rathjen said.
The company said pharmacokinetic data from the initial phase I trial of BNC210 indicated that a plateau of absorption of BNC210 was observed at doses between 600mg and 1200mg (BD: March 2, 2010).
Bionomics said that once the effect of food intake on BNC210 levels in blood was determined, doses for an expanded clinical evaluation of BNC210 would be selected.
An assessment of the levels of serum cortisol would help assess its potential as a marker of the central nervous system effects of BNC210, following the initial findings, in which subjects receiving BNC210 showed lower levels of cortisol, a stress hormone which increases in response to stress and anxiety.
Bionomics phase Ib clinical trial is expected to begin shortly after completion of this clinical study.
The company said the expanded testing of BNC210 would include evaluating the effects in a setting involving the induction of anxiety in healthy subjects and also evaluation of BNC210 effects on the brain using electroencephalograph measurements.
Bionomics said the trial would examine whether side-effects such as sedation or memory impairment, were associated with the administration of BNC210.
The first Phase I clinical trial of BNC210 indicated that BNC210 was extremely well tolerated at high doses and free of significant side-effects, the company said.
The findings, if sustained, would be “an important differentiator of BNC210 from many current treatments on the market for anxiety and depression, each of which has multibillion dollar sales annually” the company said.
Bionomics fell half a cent or 1.6 percent to 31 cents.

IMMURON

Immuron says it has signed a licencing agreement with Nycomed to distribute Travelan that reduces the risk of travellers’ diarrhoea.
Immuron said the agreement covered Australia and New Zealand and it was the intention of both parties to explore licences to further geographic territories for Travelan and further applications of Immuron’s hyperimmune antibody technology platform.
The company said Travelan would be sold under the Nycomed label in Australia and New Zealand, mainly through chemists, but woudl retain the name Travelan.
Immuron said Nycomed’s marketing team expected that sales of Travelan would “significantly increase with their marketing input” and Nycomed would make a substantial investment to increase the brand presence.
Immuron was up 0.3 cents or 4.8 percent to 6.5 cents.

SUN BIOMEDICAL OCCUPATIONAL & MEDICAL INNOVATIONS

Sun Biomedical says it will make an investment in Occupational & Medical which is in administration and has signed a deed of company arrangement.
Sun said it expected to participate in the recapitalization of Occupational & Medical, which owned patents in relation to medical syringe and syringe management technology.
Sun said Occupational & Medical had an ASX listing, but had been suspended since October 1, 2009 and appointed voluntary administrators on December 31, 2009.
The deed of company arrangement provides that Sun would make an initial contribution of $15,000 to Occupational & Medical, with an additional $115,000 payable to a creditors' trust contingent on completing a share consolidation and capital raising which would see Occupational & Medical raise sufficient funds to continue its operations.
Sun fell 0.1 cents or 50 percent to 0.1 cents.
Occupational and Medical last traded at 14.5 cents.

AVEXA

Avexa has requested a trading halt "pending the release of a price sensitive announcement in regard to Avexa's lead drug development program Apricitabine (ATC)".
Trading will resume on May 10, 2010 or on an earlier announcement.
Avexa last traded at 12 cents.