Biotech Daily

Monday March 21, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRANA UP 18%; LBT DOWN 11%**

*** PRANA: MHRI DATA SHOWS PBT2 IMPROVES ALZHEIMER'S COGNITION**

*** CITY OF HOPE TO OPTIMIZE BENITEC'S DD-RNA-I HIV COMPOUND**

*** CHEMGENEX CEO DR GREG COLLIER: 'DATA ON TRACK FOR MARCH 31'**

*** BIO-MELBOURNE BRIEFING ON CLINICAL TRIALS REPORT**

*** GENERA RECEIVES UNDISCLOSED PAYMENT FROM UNNAMED PARTNER**

*** BONE HIRES NY'S GILFORD SECURITIES AS FINANCIAL ADVISOR**

MARKET REPORT

The Australian stock market climbed 0.35 percent on Monday March 21, 2011, with the S&P ASX 200 up 16.4 points to 4642.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and three were untraded.

Prana was best, up 2.5 cents or 17.9 percent to 16.5 cents, with 694,428 shares traded, followed by Uscom up 16.7 percent to 28 cents with 12,500 shares traded and Antisense up 12.5 percent to 0.9 cents with 95.6 million shares traded.

Genetic Technologies and Universal Biosensors climbed more than three percent; Alchemia, Heartware, Prima, Sirtex and Starpharma rose more than two percent; with Psivida and Tissue Therapies up more than one percent.

LBT led the falls, down 0.7 cents or 10.8 percent to 5.8 cents, with 301,105 shares traded, followed by Sunshine Heart down 8.6 percent to 3.2 cents with 498,797 shares traded.

Cathrx, Chemgenex and Phylogica lost more than five percent; Benitec, Bionomics, Cellestis and Phosphagenics fell three percent or more; Clinuvel, Pharmaxis and Viralytics shed more than two percent; with Impedimed, Nanosonics and Resmed down one percent or more.

PRANA BIOTECHNOLOGY, VICTORIA MENTAL HEALTH RESEARCH INSTITUTE

Prana says new data shows the ability of its lead drug PBT2 to repair damage in an Alzheimer's affected brain, facilitating the restoration of cognition in Alzheimer's disease.

Prana said the findings by researchers at the University of Melbourne and Victoria's Mental Health Research Institute led by the MHRI's Dr Paul Adlard help explain the rapid improvement in cognition previously reported in transgenic Alzheimer's mice and in patients in a phase IIa clinical trial with PBT2.

The article, published in the Public Library of Sciences' journal Plos One, is entitled 'Metal Ionophore Treatment Restores Dendritic Spine Density and Synaptic Protein Levels in a Mouse Model of Alzheimer's Disease' and an abstract is available at: http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0017669.

The abstract concluded that the data suggested "that PBT2 may affect multiple aspects of synaptic health [and] efficacy".

"In Alzheimer's disease therefore, PBT2 may restore the uptake of physiological metal ions trapped within extracellular beta-amyloid aggregates that then induce biochemical and anatomical changes to improve cognitive function," the abstract said.

Prana said the article described the biochemical and anatomical changes occurring in the brains of transgenic Alzheimer's mice treated with PBT2.

The company said that after 11 days of treatment, the brains of the Alzheimer's mice showed a statistically significant increase in the numbers of spines on the branches or dendrites of neurons in the hippocampus, compared to controls.

Prana said the hippocampus was a memory centre affected in Alzheimer's disease.

The company said that increasing the number of spines was important as it permitted more neurons to interconnect with any particular neuron thereby increasing the brain's capacity to carry out learning and memory functions.

Prana said the anatomical changes to the hippocampus were also accompanied by increased levels in key proteins involved in learning, memory and neuronal growth, with the levels of many of the proteins restored to levels seen in healthy, cognitively normal animals.

Prana's head of research Prof Robert Cherny said the ability of PBT2 to promote the forming and reforming of connections between neurons was "fundamental to the repair of brain tissue damaged by [Alzheimer's disease] and the expression of key neuronal receptors and signaling proteins indicates that the repaired tissue is functional".

The company said that in a series of parallel experiments, the authors also administered PBT2 to cultured neurons and in these in vitro experiments, PBT2 was able to elicit elongation of arm-like projections from the immature developing neurons called neuritis, which could mature into either axons or dendrites of an adult neuron.

Prana said it was significant that the changes observed in the in vitro experiments were strictly dependent on the presence of copper or zinc in the growth medium, confirming that the restorative effect of PBT2 was due to its ability to deliver these metals to deficient neurons and it had previously been shown that PBT2 neutralised the toxicity of the Alzheimer's amyloid beta protein by preventing the formation of toxic aggregates or oligomers.

Prana said the data further explained how PBT2 could achieve rapid improvements in cognition by liberating copper and zinc trapped in amyloid deposits and returning those essential metals to neurons, where they are needed for normal function.

"These findings further demonstrate the unique combination of detoxification and neuronal restoration provided by PBT2 that underlie cognitive improvement in the clinic," Dr Cherny said.

Prana was up 2.5 cents or 17.9 percent to 16.5 cents.

BENITEC

Benitec says the City of Hope hospital will optimize the DNA-directed RNA interference (ddRNAi) treatment of HIV positive lymphoma patients in a phase I/II trial .

Benitec said the Duarte, California City of Hope research hospital would begin a second phase I/II study using its ddRNAi technology in lymphoma patients carrying the HIV virus and modify a range of clinical parameters.

Benitec said that from 2007 to 2010, it funded the initial development by the City of Hope of an RNA-based HIV/AIDS therapeutic molecule, one component of which was based on its ddRNAi technology, a short hairpin RNA construct targeted at a specific HIV gene.

The company said the ddRNAi-based product candidate was taken into a phase I/II pilot human clinical trial and produced promising interim safety and proof of feasibility results.

Benitec said it was not funding the study, but a successful outcome would provide further evidence of the potential of the technology for human therapeutics in general and HIV/AIDS specifically.

Benitec fell 0.1 cents or 3.6 percent to 2.7 cents with 2.6 million shares traded.

CHEMGENEX

Chemgenex chief executive officer Dr Greg Collier has told Biotech Daily that the Omapro data analysis is on track for the March 31, 2011 option deadlines.

Dr Collier said his company would complete the data in time for Cephalon to review it before March 31.

”We are very confident they’ll have time to make their decision by March 31,” Dr Collier said. “All is going well.”

Chemgenex has completed two phase II/III trials of Omapro for chronic myeloid leukemia, but its first application to the US Food and Drug Administration for patients with the T315I mutation was held up by the FDA’s Oncological Drug Advisory Committee requiring a specific diagnostic for the indication (BD: Apr 12, 2010).

Chemgenex agreed with the FDA to combine data from that trial along with the trial of chronic myeloid leukemia patients who had failed two or more tyrosine kinase inhibitors and reapply (BD: Jul 14, 2010).

Last year, the Pennsylvania-based Cephalon took an option on 19.9 percent of Chemgenex from existing investors, with Stragen International and Merck Santé SAS, with an additional 10 percent through a $15 million convertible note to Chemgenex at 50 cents a share (BD: Oct 22, 2010).

Conditions associated with the two separate arrangements included Cephalon waiving 10 percent a year interest charges on the note, pending shareholder approval which was achieved on December 21, 2010, thereby removing takeover provisions of the Corporations Act, should Cephalon proceed with the acquisition of the 19.9 percent from Stragen and Merck at 70 cents a share; and Chemgenex completing its data analysis before March 31, 2011.

A further incentive for Chemgenex to complete the analysis on time was that Cephalon would be entitled to redeem the notes if it wasn’t.

The option for Cepahlon to acquire the Stragen and Merck shares had a deadline of the later of March 31, 2011 and one week after the completion of data collection and analysis.

Dr Collier said that Cephalon acquiring the Stragen and Merck shares would not trigger a takeover bid under the Corporations Act because of the shareholder approval.

“Cephalon can exercise their option and that does not automatically trigger a takeover,” Dr Collier said.

Chemgenex fell 2.5 cents or 5.4 percent to 44 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network will provide a briefing on the Federal Government's Clinical Trials Action Group report released earlier this month (BD: March 3, 2011).
The Network said the Federal Government had promised to implement the report's recommendations as part of its broader national health reform agenda.
The Bio-Melbourne Network said that the recommendations were meant to address the key issues affecting Australia's clinical trial industry: the timeliness of clinical trial approvals; improving patient recruitment; increasing the level of support for clinical trial networks; and delivering a coordinated and reliable e-health system.
Bio-Melbourne Network chief executive officer Michelle Gallaher said the Government consulted widely with the clinical trials industry to develop this report.
"However we will see whether these recommendations ensure that Australia has a viable and sustainable clinical trials industry in the future," Ms Gallaher said.
The Bio-Melbourne Network said Nucleus Network chief executive officer Dr Andy Giddy would discuss the report at the briefing.
The Bio-Melbourne Network said Dr Giddy was a member of one of the reference groups to the Clinical Trials Action Group and he would provide a recent background to the Australian clinical trials industry, the report and its recommendations.
The Bio-Melbourne Network said the briefing would be followed by a panel discussion led by key members of the clinical trials industry and advisors to this report, including St Vincent's Institute research director Prof. Richard Fox, Cancer Trials Australia chief executive officer Marcus Clark, Chubb Insurance's Travis McIntosh and would be facilitated by JDJ Bioservices' chief medical director Dr David Crump.
The Bio-Briefing will be held at St Vincent's Institute on March 30, 2011 at 9 Princes St Carlton (corner of Nicholson and Princes Streets).
Registration is from 3:45pm.
For more information go to: http://www.biomelbourne.org/events/view/174.

GENERA BIOSYSTEMS

Genera says it has received a further milestone payment from its unnamed "top 10 global diagnostics company partner" for optimizing its human papillomavirus test.
Genera said the optimization was to run the diagnostic on the unnamed partner's instrumentation (BD: Feb 23, 2011).
The company said it had manufactured a batch of tests for use in a clinical trial on the test, currently being conducted by the partner and the payment related to the clinical trial batch passing all of the target criteria required by the partner.
Genera's chairman Fernando Careri said the human papillomavirus test had "hit all the target criteria and passed every evaluation that it has been put through so far".
"We're confident that it will continue to perform to expectations in the clinical study," Mr Careri said.
Genera said the partner has indicated that it had recruited about half the specimens required for the clinical trial.
Genera was unchanged at 28 cents.

BONE MEDICAL

Bone says it has engaged the New York-based private investment banking firm Gilford Securities as its financial advisor.

Bone said the appointment followed appointment of New York based chief executive officer Peter Young (BD: March 2, 2011).

The company said the two steps were “key elements in the implementation of [its] plans to establish US operations and leadership to advance its pipeline of new products for the treatment of osteoporosis and osteoarthritis, as well as build its visibility and support in the US”.

Mr Young said he joined Bone “because of the promise of the products it has under development”.

“All these opportunities require to fulfill that promise is effective support, recognition, and execution,” Mr Young said.

“Gilford Securities, with its expertise and reputation, is just the right match to help us establish the company’s presence in the US so that we can capitalize on the latent value I am convinced these products represent,” Mr young said.

Bone said the Gilford healthcare banking team would be led by Dr Ken Sorensen, who worked as a neuroscientist and a patent agent before joining the life sciences industry as an investment banker and hedge fund manager.

Bone was untraded at four cents.