Biotech Daily

Monday April 19, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 7%; PATRYS DOWN 10%**

*** DORON BEN-MEIR APPOINTED COMMERCIALISATION AUSTRALIA CEO**

*** FEDERAL GOVERNMENT INNOVATION REPORTS SET BENCH-MARKS**

*** PRANA 2nd DATA CUT SHOWS SIGNIFICANT ALZHEIMER'S BENEFIT**

*** BIOMÉRIEUX PAYS LBT $3.4m MILESTONE**

*** IMMURON COMPLETES BIOGARD PHASE II HIV ADJUNCT TRIAL DOSING**

*** GIACONDA WITHDRAWS EUROPEAN PATENT APPLICATION**

*** GENERA PAPTYPE HPV TEST READY FOR CE MARK**

*** IMMURON SHARE PLAN TO RAISE $1.56m**

*** CATHRX LOSES DIRECTOR DR CARRIE HILLYARD**

MARKET REPORT

The Australian stock market fell 1.4 percent on Monday April 19, 2010 with the S&P ASX 200 down 69.6 points to 4915.1 points.

Eight of the Biotech Daily Top 40 stocks were up, 18 fell, 11 traded unchanged and three were untraded.

Cellmid was best, up 0.2 cents or 7.4 percent to 2.9 cents with 500,000 shares traded, followed by Phylogica up half a cent or 5.6 percent to 9.5 cents with 78,950 shares traded.

Avexa climbed 3.85 percent to 13.5 cents with 2.3 million shares traded; Genetic Technologies was up 2.9 percent; with Cellestis and QRX up more than one percent.

Patrys led the falls, down 1.5 cents or 10.3 percent to 13 cents with 40,000 shares traded, followed by Antisense down 10 percent to 1.8 cents with 2.1 million shares traded.

Phosphagenics fell 6.45 percent; Acrux, Biota, Chemgenex, Living Cell, Mesoblast, Nanosonics and Prana lost more than three percent; Alchemia, Benitec, Cathrx, and Tissue Therapies shed more than two percent; with Bionomics, LBT and Sirtex down more than one percent.

COMMERCIALISATION AUSTRALIA

Technology innovator and director of Prescient Venture Capital Doron Ben-Meir, 44, has been appointed chief executive officer of Commercialisation Australia.

The appointment to head the Federal Government funding agency was made by Innovation Minister Senator Kim Carr at a 'Collaborating for Success' conference in Melbourne this morning.

Mr Ben-Meir told Biotech Daily that he was born in England, raised in Australia and holds a Bachelor of Science and Bachelor of Electrical and Computer Systems Engineering from Monash University.

Mr Ben-Meir said he had built six technology businesses starting in 1991 with Security Magnetics producing secure identity cards which were sold to Australia's Department of Defence and the UK's Ministry of Defence.

He also developed smart card technology and cofounded an Australian manufacturing plant for German currency printer Giesecke and Devrient.

Most recently Mr Ben-Meir said he had created Enesolve, an energy consulting business and is a director of Prescient Venture Capital and a former member of the Australian Private Equity and Venture Capital Association.

His appointment was welcomed by a range of biotechnology industry opinion leaders.

FEDERAL GOVERNMENT

In his address to the Collaboration for Success conference in Melbourne, Senator Carr released the Australian Innovation System Report setting bench-marks for innovation.

"We trail the pace-setters on a number of measures," Senator Carr said.

He said the report detailed ways to measure innovation performance, including: the number of higher degrees by research as a percentage of GDP; publications per 1,000 researchers; public expenditure on tertiary education; the number of businesses registered for the research and development tax concession; business research and development as a percentage of GDP; relative patent application numbers; investment in early stage venture capital as a percentage of GDP; and measures of links and collaborations.

The report has targets for public research funding, increasing the number of students completing higher degrees by research, increasing the number of businesses investing in research and development, a goal for a 25 percent increase in the number of businesses engaged in innovation, increases in collaboration between business, universities and research institutes as well as international collaboration.

Referring to a paper entitled Management Matters In Australia 2009, Senator Carr said people often had opinions about Australian workers, but less was asked of management.

"We are ranked six out of 16 and that's not good enough," Senator Carr said.

"Half our firms are being outperformed by competitors in India and China," he said.

"A firm is unlikely to innovate if the management just doesn't get it," Senator Carr said.

"The future will reward those firms that can change day in and day out," he said.

Senator Carr said one of the greatest needs was for international collaborations.

Asked by the conference compere ABC-TV's Kerry O'Brien about the lack of capital investment in innovation by superannuation funds, Senator Carr said he was attempting to encourage private venture capital funding and said he would be "working with the super funds".

Asked about the biotechnology sector's view that Commercialisation Australia was an "order of magnitude" low on funding, Senator Carr said he could ask for greater funding from his Cabinet colleagues "when I can demonstrate the success of the program".

PRANA BIOTECHNOLOGY

Prana says further analysis of its phase II trial of PBT2 for Alzheimer's disease shows that patients on the drug had a statistically significant improvement in Executive Function.

Prana said an article entitled 'PBT2 rapidly improves cognition in Alzheimer'sdisease: additional phase II analyses' published in the Journal of Alzheimer's Disease on April 19, 2010 was a new analysis that showed that PBT2 "was effective in reversing dementia symptoms". An abstract is at: http://www.ncbi.nlm.nih.gov/pubmed/20164561.

Prana said the analysis was conducted by the Victorian Mental Health Research Institute's Prof Ashley Bush and tracked and ranked the responses of each individual patient, rather than only groups of patients.

Previous results of the phase IIa trial, reported in The Lancet Neurology (July 2008 and an erratum in July 2009), showed that patients with mild Alzheimer's disease treated with 250mg of PBT2, experienced an overall statistically significant improvement in executive function on a neuropsychological test battery within 12 weeks of treatment.

The chairman of Prana's scientific advisory board Dr Jeffrey Cummings said that improvements in executive function was "strongly related to improvement in daily function and to the quality of the daily life of patients".

"Very few drugs in clinical development have been able to bring these benefits to Alzheimer's disease patients," Dr Cummings said.

The Journal of Alzheimer's Disease paper said the results of a post-unblinding analysis of the cognitive data that was not included in the original paper.

Prana said the objective of the analysis was to see how individual patients who were receiving PBT2 responded compared to the individual patients who only received placebo. Importantly, even placebo patients showed some improvement in the tests because of a learning effect of repeated testing, Prana said.

The company said the analysis adjusted for the learning effect and demonstrated that 81 percent of 27 patients on the 250mg dose of PBT2 responded better on the executive factor neuropsychological test battery (NTB) score than the best performing of the 28 patients on placebo. A third group of 19 patients on 50mg PBT2 was not discussed.

Prana said 41 percent of patients on the 250mg dose of PBT2 responded better on the overall composite NTB score than the best performing patient on placebo, of which executive function was one of two parts.

Asking the question: "What is the probability that any patient who showed cognitive improvement was receiving PBT2?', the paper reported a significant probability that patients who improved in executive function were probably receiving 250mg of PBT2 ($p=1.3 \times 10^{-9}$) and patients who improved their composite NTB were probably receiving 250mg of PBT2 ($p= 0.0007$).

Improvement in ADAS-Cog, a measure of memory and cognition, "almost achieved a statistically significant level in the 12 week trial" and patients who improved their ADAS-Cog score were probably receiving 250mg of PBT2 ($p=.056$), Prana said.

Mental Health Research Institute director and in Alzheimer's researcher Prof Colin Masters said the results were "very exciting given that they were achieved in mild Alzheimer's disease sufferers in a relatively short period of time".

"Based on clinical trial outcomes to date, Prana's therapeutic strategy stands up as one of the safest and most effective means of treating the disease," Prof Masters said.

The company said PBT2 targeted the pathological interaction between amyloid-beta and synaptic metal ions to prevent downstream toxic amyloid-beta oligomer formation.

PBT2 can also transfer metal ions otherwise trapped by amyloid-beta oligomers into neurons, helping to promote normal memory function.

Prana was down half a cent or 3.45 percent to 14 cents.

LBT INNOVATIONS

LBT says it has received its scheduled EUR2 million ($A2.9 million) milestone payment from French licence partner Biomérieux for its agar plate-streaking technology.
The company said it "hedged the exchange rate during 2009 and has therefore received $A3.4 million".
LBT said the milestone payment was a licencing fee payable on the third anniversary of the agreement with Biomérieux for the commercialization of its Microstreak technology.
LBT chief executive officer Lusia Guthrie said her company was "an Australian technology commercial success story".
"It is very rewarding to reach milestones in technology development and to see our Australian invention gain worldwide distribution through our international partnership with Biomérieux," Ms Guthrie said.
LBT said Microstreak was sold by bioMérieux under the brand name Previ Isola and was designed "to revolutionize front-end media processing tasks".
LBT said it would use the capital "to continue the development of a further breakthrough automated technology for medical and scientific laboratories".
In addition to milestone payments, LBT said it also received ongoing royalties based on a percentage of sales of disposable single-use Previ Isola applicators.
LBT fell 0.1 cents or 1.05 percent to 9.4 cents.

IMMURON

Immuron says it has completed the treatment phase of its phase II double-blind, placebo-controlled trial of Biogard as an adjunct therapy for HIV.
Immuron said the trial by the National Centre of HIV Epidemiology and Clinical Research at the University of New South Wales was designed to test Immuron's Biogard hyper-immune antibody product as adjunct therapy to support the immune system of HIV patients undergoing long-term treatment with anti-retroviral drugs.
The company said the trial also involved the anti-retroviral drug Raltegravir in a combination of treatment regimes
Immuron said all patients completed their treatments and samples were being processed.
The company said the trial was sponsored by the National Health and Medical Research Council through a National Centre of HIV Epidemiology and Clinical Research program.
Immuron said that during the six month treatment phase, there was "excellent patient retention and compliance, with 68 of 73 participants finishing their allotted courses".
The company said compliance was an early indication that Biogard would be acceptable for long term use and expected to release complete trial results by July 2010.
The results will include both primary endpoints of immune marker measurements and secondary endpoints of changes in plasma viral load and T cell counts.
Immuron said that if the trial results were positive, it would seek to partner with a pharmaceutical company with anti-retroviral drugs on the market that could be improved or differentiated using Biogard.
The company said Biogard was "quickly registrable … due to its suitability for classification as a generally regarded as safe (Gras) product in the US and Australia".
Immuron chief executive officer Dr Grant Rawlin said the company was "delighted that this clinical trial has proceeded so smoothly within the expected timeframe".
"We eagerly await the results, which if positive, due to the large global market for chronic support products for HIV patients, will have a positive impact for Immuron and also for the many patients being treated with anti-HIV drugs," Dr Rawlin said.
Immuron was down 0.8 cents or 10.3 percent to seven cents.

GIACONDA

Giaconda says it will withdraw its revised patent application for its Hepaconda treatment from the European Patent Office.

Giaconda said Hepaconda was a gastrointestinal treatment of the hepatitis C virus genotype 1 developed by major shareholder Prof Thomas Borody.

The company said the examination board of the European Patent Office refused to register the original Hepaconda patent application because it was too similar to an existing registered patent which uses the same combination of constituent chemicals but for a different type of treatment.

As a result, the company lodged a revised patent application to obtain European registration for its Hepaconda treatment, Giaconda said.

The company said it had advice from its European patent attorneys that its revised patent application was unlikely to obtain the support of the examination board.

Giaconda said it would withdraw its revised patent application to focus on commercializing Hepaconda in other markets.

Giaconda was untraded at four cents.

GENERA BIOSYSTEMS

Genera says its Paptype human papillomavirus assay conforms with European regulatory requirements and is ready for Conformitée Européenne (CE) mark.

The company said the European Union required self-certification that their products fulfill the essential requirements for in vitro diagnostic devices.

Genera said the Paptype detection and genotyping assay could be sold in the European Union, as well as in Australia and other regulatory authorities accepted the CE mark.

Genera chairman Fernando Careri said it was “a crucial commercial milestone”.

The company’s chief executive officer Dr Allen Bollands said that pathology companies outside Australia would be able to use Paptype, “so CE marking opens up a significant opportunity for our company”.

“An increasing number of countries recognize the value of HPV testing over and above conventional Pap smears and they are looking to incorporate it into their cervical screening schedules,” Dr Bollands said.

“While Genera's plans for Paptype involve licencing the product to a major international diagnostics company, in the immediate term we are also investigating the opportunity to make significant direct sales,” he said.

“I will be meeting with several major European HPV test users over the next few weeks as we pursue this opportunity,” Dr Bollands said.

Genera was unchanged at 68.5 cents.

IMMURON

Immuron hopes to raise up to $1,560,000 through the issue of up to 24,000,000 shares at 6.5 cents a share.

Shareholders eligible at the record date of April 16, 2010 would be able to apply for parcels of shares up to $15,000.

Immuron said the share plan would close on May 28, 2010.

The company said the funds were primarily for the clinical assessment of oral immunotherapy underway at the Hadassah Medical Centre in Israel and the development of an influenza preventative treatment both in Melbourne and Jerusalem.

CATHRX

Cathrx says non-executive director Dr Carrie Hillyard has resigned as a directors.

Cathrx said Dr Hillyard was appointed to the board on June 27, 2005 and "contributed significantly to the ongoing development of Cathrx".

The company said it would review its board structure and "consider whether the appointment of another non-executive director with the appropriate skill set was appropriate to assist with the execution of the company's transformative commercialization strategy".

Cathrx was down half a cent or 2.9 percent to 17 cents.